SNM/ACNP
GOVERNMENT RELATIONS UPDATE

Radiology RVS The House Energy and Commerce Committee adopted a one-year exemption from the recently implemented Radiology Relative Value Scale (RVS) for nuclear medicine specialists certified by American Board of Nuclear Medicine or American Board of Radiology (Special Competence in Nuclear Radiology). SNM/ACNP is continuing efforts to have similar language adopted by the Senate Finance Committee.

Expenditure Targets Despite strong American Medical Association (AMA) and specialty society opposition, the House Ways and Means Committee adopted controversial "expenditure targets" (ETs), which would prospectively set a target for physician spending in the subsequent year. If aggregate spending by physicians exceeds that target, then Congress would hold down any payment increases in the coming year. AMA calls the plan rationing; the Bush Administration and the Physician Payment Review Commission (PPRC) support ETs.

Resource-Based RVS Both the House Energy and Commerce and Ways and Means Committees have adopted slightly differing versions of budget reconciliation legislation that would implement a modified resource-based relative value fee schedule. The Ways and Means proposal would begin October 1, 1991 and be fully in place by October 1, 1996. The Energy and Commerce proposal would be phased in over four years, beginning on April 1, 1990.

FDA Revitalization Portions of Senator Orrin Hatch's (R-UT) Food and Drug Administration (FDA) Revitalization bill were not incorporated into budget reconciliation legislation considered by the Senate Labor and Human Resources Committee last July. This bill would establish a public/private trust fund to pay for a consolidated FDA building/campus; establish a Senior Health Science Corps to recruit and retain senior scientific personnel (with enhanced salaries); set aside $18 million to help small businesses comply with FDA regulations; authorize $10 million for a public/private sector partnership in biotechnology; authorize training grants and loans for new scientists studying FDA regulatory issues; authorize funding for greater automation of the FDA; and set a floor of $500 million for all of the activities of the FDA. Staffers for Senator Hatch and Senator Edward M. Kennedy (D-MA) have indicated that the bill will be considered separately, perhaps as early as this fall.

Physician Referrals The House Ways and Means Committee has incorporated a modified version of Representative Fortney H. (Pete) Stark's (D-CA) physician referral bill in its budget reconciliation package (see page 1579).

SPECT Coverage SNM/ACNP has informally inquired at the Health Care Financing Administration (HCFA) regarding the regional inconsistencies in single photo emission computed tomography (SPECT) Medicare coverage. HCFA will look into the problem to determine if clarification can be made to the carriers informally, rather than initiating the national medicare coverage process, which can be quite time-consuming.

DOE NM Research The House and Senate have passed fiscal year (FY) 1990 appropriations bills for the Department of Energy (DOE) that highlight positron emission tomography (PET) research but do not specifically allocate increased funding for the beleaguered DOE Nuclear Medicine Research program. Both the House and Senate passed bills that would allocate $37,645,000 for nuclear medicine research in FY 1990, just $145,000 more than the level appropriated for FY 1989. SNM/ACNP has testified for a $5 million increase to $42.6 million (see *Newsline*, July 1989, p. 1148). Several pork barrel projects are included in the Senate bills.

FDA User Fees Both the House and Senate Appropriations Committees have rejected the concept of FDA user fees for FY 1990, as well as proposals to charge "registration" fees to each entity regulated by the FDA. Senator Kennedy's staff had floated a proposal to require all drug, medical device, cosmetic, and food companies (US or foreign) to pay yearly establishment registration fees to the FDA for any lab, factory, warehouse, etc. where these products are manufactured, processed, packed, or held. The proposal is opposed by industry. Both bills

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DPA Coverage Reportedly, HCFA *will not* issue a directive to withdraw Medicare coverage for single photon absorptiometry (SPA) or to continue non-coverage for dual photon absorptiometry (DPA). On the contrary, the issue of coverage for these modalities may be referred back to the Office of Health Technology Assessment (OHTA) for further study, since OHTA's initial study, dated 1986, is based on outmoded data.

DPA Study In its reconciliation package, the House Ways and Means Committee adopted a provision calling for a Health and Human Services (HHS) study on the issue of Medicare coverage for dual-energy X-ray absorptiometry, DPA, and quantative computed tomography (QCT), when used for estrogen-deficient women, patients with vertebral abnormalities, patients receiving long-term steroid therapy, and patients with primary hyperparathyroidism.

NRC Petition SNM/ACNP has formally filed a Petition for Rulemaking Change with the Nuclear Regulatory Commission (NRC) that would alleviate problems created by the Part 35 re-write, which prohibits the use of non-investigational new drug, non-new drug application radiopharmaceuticals in clinical practice (see page 1584). The existing regulations essentially eliminate the practice of medicine and the practice of pharmacy. NRC is currently reviewing the petition and will publish it in the *Federal Register* for public comment. SNM/ACNP members will be encouraged to support the petition through letters to the NRC.

NRC QA Rule NRC staff are still hashing out final details of a quality assurance proposed rule for medical use licensees (see page 1584). The proposal will be designed to "reduce the chance of misadministrations." SNM/ACNP have repeatedly argued that additional standards are unnecessary and intrusive. The proposal will have a 90-day public comment period and will invite licensees to conduct a pilot study using the proposal. SNM/ACNP will initiate a large grassroots response to the NRC proposal.

OSHA Worker Protections The Occupational Safety and Health Administration has issued a proposed regulation for universal precautions for protecting an estimated 5.3 million workers against the AIDS and hepatitis B viruses and other blood-borne pathogens. It would require employers to evaluate routine workplace tasks and procedures that involve exposure to blood or other potentially infectious materials, to identify workers performing such tasks, and to reduce risk. It also would require employers to offer free hepatitis B vaccines to workers and to provide training and protective equipment. The estimated cost to each hospital would be $32,875; the cost to teaching hospitals would be more.

PET Coverage HCFA will be asking OHTA to conduct a comprehensive review of the efficacy of PET studies for certain clinical indications to assess whether or not PET should be covered under Medicare. OHTA will solicit comments from the public as well as the National Institutes of Health (NIH), FDA, and other Federal agencies. The review process is likely to take up to two years.

LLRW Sites In passing the FY 1990 DOE Appropriations bill, the House of Representatives has authorized $5 million for the low-level radioactive waste program. The bill mandates the creation of an independent state compact association that would "promote an effective and efficient national system for management and disposal of waste. . . including the consideration of agreements which could lead to a reduction in the number of waste facilities constructed." Although several bills aimed at reducing the number of compacts have been introduced in Congress, this is the first provision of this sort passed by the House.

Medical Waste The Medical Waste Tracking Act went into effect on June 22 for five states: New Jersey, New York, Connecticut, Rhode Island, and Louisiana as well as Puerto Rico and the District of Columbia (see *Newsline*, Sept. 1989, p. 1431). Louisiana and the District of Columbia have since asked to be withdrawn. The new law requires a cradle-to-grave tracking system for wastes such as cultures, blood products, human pathological wastes, contaminated animal carcasses, and sharps. SNM/ACNP opposed the regulation.

NCI Diagnostic Committee A new Diagnostic Decision and Implementation Committee has been established at the National Cancer Institute to oversee the movement of promising new diagnostic procedures from the research to clinical setting. The Committee will also spur cooperation among government, academia, and industry regarding cancer diagnostic development. This could have positive spin-off effects for nuclear medicine.

Alzheimer's Research The Federal Advisory Panel on Alzheimer's Disease, a 15-member congressionally mandated committee has recommended that the US more than double its spending

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on Alzheimer's research to $300 million. This increase from the current $123 million budget would increase Alzheimer's research centers from 12 to 15, and fund half of NIH research applications in this area. (Currently only 20% are funded.) Senator Howard Metzenbaum (D-OH) recently introduced S. 1255, which calls for $179 million for Alzheimer's research and training. If these increases are enacted, there will be more funding available for nuclear medicine diagnostic research applications.

Veterans Care Congress has enacted and President Bush has signed into law a provision for $340 million in emergency funds for veterans health. The emergency funds, which had been held up due to political infighting, will allow Veterans Administration (VA) hospitals to rebuild their staffs and physical plants. The VA indicates that its top priority will be to rejuvenate its alcohol and drug abuse programs.

New SNM/ACNP Assistant Director Valerie A. Fedio joins the SNM/ACNP Joint Washington Office as assistant director of Government Relations. With a nursing degree from Georgetown University and a Masters degree in Health Services Administration from the Sloan Program at Cornell, Ms. Fedio brings with her a knowledge of the health care field. While in past positions as a health care consultant, including a stint at the American Hospital Association, she gained valuable experience in health policy analysis. Ms. Fedio will manage the new SNM/ACNP Key Contact program and will assist in the various issues SNM/ACNP faces before Congress and the regulatory agencies.

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bility to monitor appropriateness should be in the hands of the physicians most capable of making those decisions."

Organizational Support and Opposition

In addition to the AMA, the American Society of Internal Medicine, the Americal Hospital Association, the American College of Cardiology, and the American College of Physicians are on record as opposed to the Stark bill, though some would support less rigorous Federal intervention. The American Society of Clinical Pathologists, the American Clinical Laboratory Association, and the American College of Radiology (ACR) are among those who have supported the measure. ACR adopted a resolution in September, 1988 that "Referring physicians should not have direct or indirect financial interest in diagnostic or therapeutic facilities to which they refer patients."

Dr. Handmaker expressed concern about the implications of ACR's endorsement of the Stark bill. Acknowledging the potential for abuse, he wrote, "...the appropriate use of diagnostic imaging procedures has been and should always be the responsibility of practicing radiologists, not the Federal government. Nor should the use of these procedures be reduced to a purely economic equation....The ACR resolution endorses the position that physicians who invest in imaging centers are accepting bribes, while radiologists and hospitals who own equipment never influence referrals or perform unnecessary exams."

Rep. Stark's critics are not against eliminating abuses in referrals, but they consider his bill an inappropriate and ineffective way to achieve that. Dr. Handmaker suggested that the various professional medical organizations should establish programs to ensure quality outpatient services before the government attempts to. "Gross misuse of labs is easily discernable by everyone. State boards can obviously see where there is this misuse. If this is what [Stark's] talking about, this is stuff that should be gotten rid of," said Dr. Meckelnburg. "But some of the gray areas are never going to be gotten rid of because the science is not absolute."

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References

1. Todd JS, Horan JK. Physician Referral — The AMA View. JAMA 1989;262:395-396
2. Morreim EH. Conflicts of Interest, Profits and Problems in Physician Referrals. JAMA. 1989;262:390-394
3. Stark,F. Physicians' Conflicts in Patient Referrals. JAMA.1989;262:397
4. Medicare and Medicaid Programs: Fraud and Abuse OIG Anti-Kickback Provisions. *Federal Register* 1989;54:3088
5. Handmaker, H. Support for Stark bill resembles hypocrisy more than Hippocrates. *Diagnostic Imaging.* 1989;11:51-52