

COMMENTARY

SNM/ACNP GOVERNMENT RELATIONS UPDATE

NUCLEAR REGULATORS

Congressional Hearings.

Subcommittees in the House and Senate are expected to hold hearings before the end of April on the role of the Nuclear Regulatory Commission in assuring safety in radiation medicine following charges of laxity in *The Plain Dealer*, a Cleveland newspaper.

In informal meetings with subcommittee staffers January 29 and February 2, physicians representing SNM and ACNP gave House and Senate staffers their perspective. Ohio Sen. John Glenn has indicated interest in untangling the roles of the NRC and the Food and Drug Administration. If regulation of medical radiation is consolidated, the Senate's leaning is to make the NRC the primary agency.

Rep. Mike Synar of Oklahoma seems intent on scrutinizing the adequacy of radiation control programs in the so-called "agreement states" that have assumed some of the NRC's responsibilities. Concerned about the consistency and adequacy of state programs, Congress may seek a stronger, overarching role for Federal regulators.

Licensing Fees. The NRC received comments from nearly 100 groups and individuals in response to the ACNP and SNM petition seeking relief from increased licensing fees. Federal law required the NRC to begin recovering its entire operating budget in 1992 through fees charged to licensees. ACNP and SNM proposed fees based on a sliding scale, exemptions for not-for-profit and teaching medical centers, and other changes for medical licensees. The American College of Radiology, the Department of Veterans' Affairs, the American Hospital Association, and other groups supported the petition, arguing among other things that hospitals and other medical providers have only a limited ability to pass on the costs of increased fees to patients. Those who opposed the petition, including a variety of nuclear power concerns, American Airlines, the Hawaiian Sugar Planters' Association, and the Colorado Division of Radiation Control, argued that to reduce fees for hospitals would only increase fees to other types of licensees who also provide some kind of beneficial service to society. NRC should publish a final decision on licensing fees by May.

Radiopharmacy Regulations. The NRC is putting the finishing touches on a proposed rule for preparation, trans-

This commentary on regulatory developments, health care reform measures, radioactive waste disposal and other issues affecting nuclear medicine comes from a report by the Joint office of Government Relations of The Society of Nuclear Medicine and the American College of Nuclear Physicians at SNM's Mid-Winter Meeting in February.

fer, and use of reactor-produced radioisotopes for medical use. The proposed rule is a response to a petition on radiopharmacy filed by ACNP and SNM in 1989. The proposed rule would allow departures from radiopharmaceutical package inserts and acknowledge "authorized nuclear pharmacists" who, along with authorized physicians, would be allowed to compound radioactive drugs. The

rule would also make clear the appropriateness of using reactor-produced radionuclides in biologic compounds and in human research.

HEALTH CARE POLICY

Medicare. Payments for nuclear medicine will drop by an average of 10% in 1993 under the Medicare fee schedule published in November. ACNP and SNM responded in January to the Health Care Financing Administration on several fronts, including a call for higher relative value units, or RVUs, for calculating reimbursement rates for nuclear medicine procedures. In comments to HCFA, ACNP and SNM argued that RVUs for nuclear medicine don't reflect the true value of such procedures since the government failed to use nuclear medicine data to derive them. SNM and ACNP are gathering data to support upwardly revised RVUs.

As for concerns about the time and expense of complying with regulations for the medical use of radioisotopes, HCFA's response is that no information exists to keep track of these expenses. ACNP and SNM suggested two sources: user fee schedules from the Nuclear Regulatory Commission and regulatory impact estimates from the President's Office of Management and Budget.

Clarifying a payment policy at the request of SNM and ACNP, HCFA has indicated that it will provide separate payment for the pharmacologic stress agent I.V. Persantine used during cardiovascular imaging procedures performed in free-standing settings.

Bans on Self-Referral. Two bills introduced by Democratic Congressman Pete Stark of California include prohibitions on self-referral for all medical services. The new version of Rep. Stark's health reform bill extends Medicare's ban on self-referral to "designated health services" including radiology. The Comprehensive Physician Ownership and Referral Act of 1993 prohibits self-referral for all services with

exceptions for procedures provided in the physician's office, under the personal supervision of the physician, or designated as "periodic, sporadic or part time."

House Republicans introduced the Action Now Health Care Reform Act of 1993, which also extends self-referral prohibitions to services including diagnostic imaging.

ENVIRONMENTAL PROTECTION AGENCY

Clean Air Act. The EPA in December announced plans to exempt medical facilities and other non-power NRC licensees from national standards for radionuclide air emissions following completion of a survey showing that 99.5% were in compliance with EPA's National Emissions Standards for Hazardous Air Pollutants (NESHAPS). A final rule is due any time.

ENERGY DEPARTMENT

NBTF. The Department of Energy told SNM and ACNP to expect the Request for Proposal for the National Biomedical Tracer Facility in mid-March. William Happer, director of energy research met with physicians and scientists representing ACNP and SNM representatives in January and Robert Wood, PhD of the Office of Health and Environmental Research attended a February SNM meeting to discuss the status of the NBTF. As a result of those meetings, it is clear that DOE will seek funding for an "interim solution" to upgrade the Brookhaven Linac Isotope Producer while the NBTF is under development. Concerns persist, however, that the DOE will use the BLIP upgrade as an excuse to avoid further support for the NBTF. ACNP and SNM urged the DOE to issue an RFP for the interim proposal and have potential sites peer-reviewed (see story on p. 13N).

Molybdenum-99. ACNP and SNM also offered assistance to the DOE in working with Congress to resolve statutory questions regarding isotope production. If the DOE begins marketing molybdenum and other isotopes distributed by Nordion, Inc., a private company in Canada, under the North American Free Trade Agreement, the department could be in violation of its policy against competition with the private sector. The department's non-compete policy needs clarification. A Congressional subcommittee under Rep. Mike Synar of Oklahoma continues its scrutiny of the Energy Department's isotope production program and an oversight hearing is expected to take place this month.

FOOD AND DRUG ADMINISTRATION

Radiopharmaceuticals. The FDA in December asked the American Medical Association to help organize an interspecialty meeting on the regulation of medical radiotracers.

No date has been set for the meeting and organizers have kept the agenda quiet. Specialties likely to be invited include cardiology, neurology, pathology, oncology, as well as nuclear medicine and radiology.

LOW-LEVEL RADIOACTIVE WASTE

Nebraska. Local voters overwhelmingly rejected a plan by the Central Interstate Compact Authority to site a low-level waste repository in Boyd County, Nebraska. With 93% of county citizens against the plan, Gov. Ben Nelson indicated the state would go to court if necessary to seek the removal of Boyd County from consideration. In addition to Nebraska, the Central Compact includes Arkansas, Kansas, Louisiana and Oklahoma.

Illinois. An independent commission aborted a five-year, \$84 million effort to select a low-level waste site for the Central Midwest Compact of Illinois and Kentucky. The Illinois Low-Level Radioactive Waste Siting Commission ruled that the proposed site did not meet several statutory criteria, including protection of the public water supply. Meanwhile, the Illinois legislature approved a measure in January that would make it easier for the state to establish a low-level waste repository by shifting to local communities the burden of proving that an area is unfit. At this writing, Illinois Gov. Jim Edgar had yet to sign the bill.

California. Just before President Bush left office, his Interior Secretary agreed to transfer a 1000-acre tract of Mojave Desert proposed for a low-level radioactive waste burial site to California. That would have allowed the state to issue a license to U.S. Ecology to begin developing the Ward Valley facility. But several environmental groups succeeded in getting a temporary restraining order from a federal district judge in San Francisco. The groups argued that development of Ward Valley could encroach on the habitat of the desert tortoise, a "threatened" animal under the Endangered Species Act. The Ward Valley facility would serve the Southwest Low-Level Radioactive Waste Compact of Arizona, California, North Dakota, and South Dakota.

ACNP and SNM signed on with U.S. Ecology in a lawsuit last year to push California into deciding whether to license the proposed waste site. An appellate court in California later ordered three state agencies to take appropriate steps to enable either approval or denial of a license by October 1992. At last word, the appellate court was still reviewing the arguments against issuing the license.

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