



# Congress May Challenge NRC

The American College of Nuclear Physicians (ACNP)/Society of Nuclear Medicine (SNM) Government Relations Office is closely monitoring the following issues affecting nuclear medicine in the coming months ahead.

## Congressional Hearings on the NAS-IOM Report

The House of Representatives' Commerce Committee, Energy and Power Subcommittee has expressed interest in seeing the Nuclear Regulatory Commission (NRC) address the issues raised in the National Academy of Science's Institute of Medicine (NAS-IOM) report, which recommended terminating the NRC's Medical Use Program and shifting control to the states. The hearings could potentially take place this fall.

In preparation for these hearings, the ACNP/SNM Government Relations office has been coordinating grassroots efforts, including a letter writing campaign to members of the subcommittee stressing the importance of a hearing to address the NRC's role in regulating nuclear medicine. The office has also been meeting with members of the subcommittee staff to brief them on the nuclear medicine specialty and the NAS/IOM recommendations.

In response to a letter sent by six members of Congress a few months ago, the NRC briefly indicated that they had not reached any conclusions about the NAS/IOM report and could not answer the questions posed by the members at this time. While no legislation will be introduced by Congress this year, much of the preparation and work being done is in anticipation of more legislative activity in the 105th Congress convening in January 1997. If you are interested in contacting congressional representatives on this issue, please contact David Nichols in the Government Relations Office at (703) 708-9000.

## Syncor Challenges PET Regulations in Court

On July 23rd, oral arguments were presented in U.S. District Court in Washington, D.C. in the case of Syncor, ACNP/SNM and the American Pharmacy Association versus Donna Shalala, Secretary of the Department of Health and Human Services, over the regulation of PET radiopharmaceuticals by the Food and Drug Administration (FDA). Syncor et al. contends that the FDA's February 1995 *Federal Register* notice forbidding the onsite compounding of PET radiopharmaceuticals amounted to a new FDA regulation which in essence forbade all compounding, a procedure central to the practice of pharmacy, as well as radiopharmacy.

Alvin J. Lorman, counsel for the plaintiff, argued that the FDA's actions constituted a major digression from the Food, Drug and Cosmetic Act for which there was no Congressional approval. In their defense, the FDA argued that PET compounds were always considered new drugs by the FDA and thus were always subject to regulation as such. Counsel for the FDA stated that, in the past, the FDA had used their discretionary

enforcement prerogative in choosing not to enforce regulations, and this recent action merely reflects a change in policy. Judge Emmet Sullivan presided over the case and promised a decision before September 21, 1996, the date these new restrictions would take effect.

## Senate Confirms Two New NRC Commissioners

The Clinton administration has taken steps to fill the two remaining vacant positions on the NRC. On July 12, 1996, President Clinton announced his intention to nominate Nils J. Diaz, PhD, of Florida and Edward McGaffigan, Jr., MS, of Virginia to be members of the Nuclear Regulatory Commission. On August 2, 1996, following a very brief and noncontroversial confirmation hearing, the Senate confirmed the nominations.

Diaz is presently a professor of nuclear engineering sciences at the University of Florida (Cite City) and director of the Innovative Nuclear Space Power and Propulsion Institute for the Ballistic Missile Defense Initiative. He holds an advanced degree in nuclear science from the University of Florida.

McGaffigan is currently a senior policy advisor to Senator Jeff Bingaman (D-NM) and has worked in his office since 1983. McGaffigan holds an advanced degree in physics from the California Institute of Technology and in public policy from Harvard University's Kennedy School of Government. Both new Commissioners are anticipated to be in office by the September 30, 1996.

## SNM and ACNP Response to HCFA Rule

The ACNP and SNM have expressed their concern over payment policies for graduate medical education being proposed by the Health Care Financing Administration (HCFA). In a proposed rule issued earlier this year, HCFA issued a proposal—prompted by congressional legislation—that would limit the amount of funding available for education beyond the years required for a primary specialty. The effect on nuclear medicine could be severe because HCFA would only reimburse at 50% for latter years of training. For example, if a resident focused on a primary specialty and then wished to obtain specialty training in nuclear medicine, the nuclear medicine section would receive only 50% of their current funding levels.

The ACNP and SNM urged HCFA to consider including the "plus-one" provision in their payment schedule to cover those residents wishing to obtain specialty training in a second approved program of a combined training program. This change would allow for continued stability in the number of available nuclear medicine specialists and would also encourage physicians in other combined training programs to complete the training in a minimum number of years after completion of the longer first program.

—David Nichols, Associate Director of the ACNP/SNM Government Relations Office