



# Congress Puts Pressure on NRC

Over the past month, several actions have occurred within the Nuclear Regulatory Commission (NRC) and Congress that could be beneficial to nuclear medicine. The ACNP/SNM Government Relations Office has been tracking these developments and responding to governmental leaders.

## Congress Holds NRC Oversight Hearing

On September 5, the NRC's five Commissioners appeared before the House Commerce Committee's Energy and Power Subcommittee for an NRC Oversight Hearing. Although the hearing focused mainly on the operations and problems at the NRC's power plants, the issue of over-regulation in medicine was also discussed. In his opening statement, Chairman Dan Schaefer (R-CO) mentioned nuclear medicine as one of the items that needs to be examined in the NRC's regulatory programs.

During the questioning, Rep. Stupak (D-MI) brought up the National Academy of Science's Institute of Medicine (NAS-IOM) report and its finding that NRC's Medical Use Program is unduly burdensome and overly prescriptive. He asked what the NRC's response was and when would they finish their review of the NAS-IOM recommendations.

NRC Chairman Shirley Jackson responded that in the commissioners' review of the NAS-IOM report, they have explored two avenues: surrendering authority over nuclear medicine regulation, and rewriting the current regulations to address some of the concerns expressed in the report. Jackson said that the NRC should finish their review late this year or early next year.

Rep. Tom Coburn (R-OK) continued questioning the by asking Chairman Jackson why the NRC will need a full year to review the NAS-IOM report. Jackson said the previously vacant spots on the Commission added to delays and that the appropriate response might involve legislative change. Rep. Michael Bilirakis (R-FL) questioned Jackson about the dichotomy of regulators involved with regulating byproduct materials. In his questioning, Rep. Bilirakis aimed to establish that 90% of byproduct material used in medicine is currently successfully regulated by the states. In her answer, Chairman Jackson effectively dodged the question and re-routed Bilirakis' line of questioning by explaining the state/federal regulation breakdown of the Agreement State and NRC State programs. Overall, Rep. Bilirakis was informed of the problems in the nuclear medicine community, and in his final question asked if physicians felt over-regulated.

The hearing demonstrated that there is Congressional support for such reform and proved that the letters and phone calls sent by the nuclear medicine community have been helpful.

## Congress Passes Energy and Water Appropriations Bill

The Energy and Water Appropriations bill, containing funds for the Department of Energy's (DOE) Medical Applications research was passed by the Congress and signed by the President on September 30 (P.L. 104-206). It contains significant funds for

nuclear medicine research through the DOE. Within the Medical Applications budget for the DOE are six project areas that receive funding each year. For FY 1997, the medical applications budget received a slight increase in funds from FY 1996.

Program area	FY 1996	FY 1997	Net Increase
Radioisotope development	\$2,713,000	\$2,721,000	+\$8,000
Radiopharmaceuticals	\$9,549,000	\$9,783,000	+\$234,000
Instrumentation	\$5,799,000	\$6,092,000	+\$293,000
Clinical feasibility	\$1,913,000	\$2,031,000	+\$118,000
BNCT	\$10,198,000	\$9,727,000	-\$471,000
Molecular nuclear medicine	\$5,345,000	\$6,366,000	+\$1,021,000

## Title VII Funding for Technologists

The House of Representatives completed action on the Labor, Health and Human Services Appropriations Bill (HR 3755), which provides appropriations for training health professionals and placing them in underserved areas. The House recommended funding of approximately \$290 million for 1997. This is \$31.275 million above 1996 funding. Of this total allocation for the health professions, the committee approved \$3.8 million for allied health special projects that is \$410,000 above the 1996 level.

The House appropriations bill identified areas such as community-based programs, expanding enrollment, developing curricula in areas such as geriatrics and establishing interdisciplinary training. The Senate Appropriations Committees are still considering funding for Health Professions. The Senate is expected to arrive at a funding figure somewhat below the House allocation. The ACNP/SNM Government Relations Office, however, has not seen any indication that the Senate's smaller allocation would affect the allied health projects funding.

## FDA Fast Track Initiative

The ACNP and SNM, together with the Council on Radionuclides and Radiopharmaceuticals (CORAR) and the National Association of Cancer Patients (NACP) are pushing forward with an initiative to include diagnostic pharmaceuticals and radiopharmaceuticals for cancer into the Food and Drug Administration's (FDA) fast track approval process. Since the agency already approves therapeutic cancer drugs on a fast track basis, the nuclear medicine coalition has told Congress, Vice President Al Gore, and the FDA that including diagnostics would enhance the end result. While congressional staff have been supportive of including this area in an ongoing initiative, the FDA has reacted with guarded optimism. FDA staff are currently reviewing the issue, and initial staff meetings are expected by the end of October.

—David Nichols, associate director of the ACNP/SNM  
Government Relations Office