



## ACNP/SNM Work to Amend FDA Reform Bill

**T**hree provisions in the current Food and Drug Administration (FDA) reform bill (S. 830) were submitted to the U.S. Senate for consideration this past July.

PET section 619 of S. 830, supported by Senator Ted Stevens (R-AK) and Bill Frist (R-TN), provides relief for the compounding of PET drugs under the Food Drug and Cosmetic Act. The legislation allows PET drugs to be compounded in accordance with state law for a patient, research, teaching or quality control based on a physician's prescription.

The bill also requires that drugs be compounded in accordance with the United States Pharmacopeia standards. This section also nullifies the recent regulations published by the FDA regarding Current Good Manufacturing Practice Guidelines for PET.

Compounding section 808 of S. 830 clarifies the ability of a physician or pharmacist to compound drugs under state law. There are, however, several scenarios that would prevent a physician or pharmacist from seeking relief under the compounding provisions. In addition, the American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM) have concerns about specific language that would maintain a level of jurisdiction for the FDA under compounding provisions.

The ACNP and SNM had provisions inserted that would allow PET an exemption from the above-mentioned provision (section 619) and to have radiopharmaceuticals excluded altogether from this section on compounding. These provisions were inserted due to the work of the Government Relations Office and the belief of the ACNP/SNM leadership that the compounding language as inserted into the bill would worsen the situation for radiopharmaceuticals.

An amendment developed by the Council on Radionuclides and Radiopharmaceuticals and sponsored by Senators Ted Kennedy (D-MA) and Judd Gregg (R-NH) (Section 610 of S. 830), requires the FDA to develop new regulations for the approval of radiopharmaceuticals that recognize the unique characteristics of these agents. This legislation is designed to improve the approval process, allowing for more drugs to come to the medical market.

After U.S. Senate consideration, the legislation will undergo review by the U.S. House of Representatives. Because the legislation is attached to the Prescription Drug User Fee Act, it must be passed by September 30, before the new fiscal year.

### NRC Outlines Reform Plan in San Antonio

Dr. Donald A. Cool, Director of the Division of Industrial and Medical Nuclear Safety at the U.S. Nuclear Regulatory Commission (NRC) attended the SNM Annual Meeting in San Antonio to discuss reform of the agency's medical program.

Dr. Cool highlighted the NRC's staff requirements memorandum mentioned in *Newsline* (see the May 1997 issue of *JNM*, page 40N) and heard comments about the importance of par-



Donald A. Cool, PhD (left), Director of the Division of Industrial and Medical Nuclear Safety at the NRC, addressed Michael D. Devous, PhD and SNM Annual Meeting attendees on the NRC regulatory reform this past June.

ticipation from medical groups in the process.

The agency is now moving forward with a reform plan that will revise the regulations for nuclear medicine currently contained in 10 CFR 35. This process will take approximately two years with a final rule in place near June 1999. The SNM has been and will continue to work closely with the agency staff to ensure timely and meaningful input into the process. In addition to written comments to the agency, the SNM expects to participate in at least two workshops with agency staff over the next two years.

### Energy and Water Appropriations Moves Forward

Both the House and Senate have completed work on an appropriations bill that would provide funding for the Department of Energy (DOE) Isotope Production Program. The DOE has requested \$21.7 million for isotope production in fiscal year 1998 with \$10.9 million of that for accelerator operations at Brookhaven, Los Alamos, Oak Ridge and Richland.

The Senate removed \$4 million of that funding however, jeopardizing the production of research isotopes such as  $^{213}\text{Bi}$ , as well as the funding for a year-round production of other valuable isotopes being produced at both Brookhaven and Los Alamos.

The House cuts were much more severe, eliminating almost \$10 million from the isotope production budget, and jeopardizing both the research programs and the  $^{99}\text{Mo}$  production program.

The SNM is working closely with staff on both the House and Senate to restore that additional funding to assure that research isotope production will continue. The final step in the process, which will be completed this month, is for a conference committee. This conference is an opportunity for members of the House and Senate to work out the differences between the two bills. Because of the opportunity for compromise, the SNM is working to secure funding for research production

first, with any available funds left over to be allocated for <sup>99</sup>Mo production. Based on DOE estimates, the SNM has proposed that \$11 million be earmarked for these research programs.

These provisions, which are part of the larger Energy and Water Development Appropriations bill, are expected to be addressed by the full House and Senate over the next month.

#### **Allied Health Funding, Title VII**

The House Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies as well as the full House Appropriations Committee have forwarded their recommendations for the funding of the Allied Health Project Grants. The funding for Allied Health received an increase to \$3.926 million and the Health Professions Training grants increased from \$292.8 million to \$306.5 million.

The House is expected to consider the bill this month with the Senate action expected shortly afterwards. The funding is then used to support grants from educational institutions for the training of allied health personnel such as nuclear medicine technologists.

The Clinton administration remains concerned about approving individual line items in the appropriations bills, such as allied health funding. Legislation was proposed last year that would have clustered all health professions training under one line item in the budget, then allowed staff at the Health Resources and Services Administration to make determinations about funding levels in each area.

This cluster approach is still being discussed now and the Society of Nuclear Medicine-Technologist Section (SNM-TS) has supported it. In testimony submitted by the Allied Health Roundtable, in which the SNM-TS participates, the group supported a cluster of allied health, rural health and geriatrics. These three groups would be clustered together under one line item, potentially creating an opportunity for more allied health funding in the future. This issue is still being debated, however, and it is unclear whether Congress will address this issue this year in spite of its continuing to appropriate funds based on individual line items.

—David Nichols is the director of the ACNP/SNM government relations office

#### **Brookhaven Changes Management**

*(Continued from page 20N)*

Brookhaven, but were working under an outside contractor on the Brookhaven site.) All Brookhaven employees attended safety seminars during the lab shutdown.

#### **Public Pressure for Safety Measures**

In one of his most highly visible acts since taking office in March, Peña's dismissal of AUI was based on a history of highly publicized incidents of environmental and safety lapses at Brookhaven. As cited in the DOE report, Brookhaven was declared a Superfund site in 1989. A mishap at one of the experimental stations near the reactor caused a small electrical fire in 1994 that caused a negligible amount of radiation to be released. Brookhaven's beam reactor has also been leaking a small amount of tritium into the groundwater on the site.

"We found multiple indications of safety taking a back seat to science," said Glenn Podonsky, DOE Deputy Assistant Secretary for Oversight whose department conducted the evaluation. The report criticized Brookhaven for not dealing with the tritium leak as a top priority when tritium was first detected in a monitoring well south of the reactor in 1986. In 1992, an engineering analysis recommended building three additional wells further south of the reactor. These wells were not installed, according to the report, for reasons that are unknown. "In 1994, BNL made a commitment to the Suffolk County Department of Health Services...to install two monitoring wells south of the HFBR, but did not follow through," said the report. The next year, Brookhaven managers decided to delay installation of the wells because of funding reductions.

The report also criticized the DOE for not following up on the tritium leak. "No one from the Department validated that the monitoring wells had been built," said Podonsky. "There was a calamity of errors that took place, and our report stressed that improvement is needed within the DOE in terms of account-

ability for the managers that the DOE goes into contract with."

The tritium plume currently stretches 1.5 miles south of the reactor and contains a total of 10 curies of tritium, according to Kara Villamil, a press officer at Brookhaven. Since mid-May, water has been pumping into the southern-most tip of the plume, which has diluted the concentration of tritium to 6000 picocuries/liter. (The EPA's drinking water limit is 20,000 picocuries/liter.) The diluted tritium will then be pumped back to a recharge basin, where it will inch southward again, winding up in the southern-most site in 19 years. By that time, the tritium, with a half-life of 12.3 years, will have a concentration of 2000 picocuries/liter. The process, called the Tritium Plume Recovery Plan, has been approved by the Suffolk County and New York State Departments of Health and the EPA. All three agencies are in agreement that the plume poses no threat to the drinking water wells serving the nearby community, said Villamil.

Senator Alfonse D'Amato (R-NY) has promised to commit \$6 million in Brookhaven funds to hook up houses closest to the plume to the public water supply. "This funding completely ignores the fact that the tritium has not left this site," said Mona Rowe, a spokesperson for Brookhaven. Senator D'Amato and other politicians are being swayed by a small, but vocal, group of environmental and community activists who have been picketing the reactor site. Rowe said anywhere from 2 to 80 protesters have been gathering on a regular basis to lobby for the permanent closure of the reactor.

#### **Delays in Nuclear Medicine Research**

The climate of public discontent and the shutdown of the reactor has interrupted a large body of research involving radionuclides used in nuclear medicine, as well as projects in other fields. "We were supposed to be celebrating Brookhaven's 50th Anniversary this year—which is particularly relevant to nuclear medicine since over 80% of radioisotopes used in nuclear

*(Continued on page 43N)*