Representatives Richard Burr (R-NC), Gary Condit (D-CA) and Tom Delay (R-TX) have circulated legislation for introduction in the 105th Congress that would provide important protection for physicians and pharmacists against unwarranted regulation by the Food and Drug Administration (FDA). The legislation clarifies that states, not the FDA, have regulatory authority over pharmacy compounding. The bill also extends to licensed physicians involved in compounding.

In addition to compounding provisions, the legislation would also withdraw FDA proposed regulations of PET drug products. The legislation would make the FDA proposal to expand regulation of PET drugs null and void, and return this issue to the state boards of pharmacy.

Representative Burr’s office is currently gathering co-sponsors and ACNP and SNM members are urged to contact their own members of Congress, encouraging them to co-sponsor the bill. For a copy of the legislation and a sample letter to send to your member of Congress, contact Leonard Getzin, ACNP/SNM government relations associate coordinator at (703) 708-9773.

Government Relations Committee Meets in Palm Springs

The ACNP/SNM Government Relations Committee met on February 8, 1997, in Palm Springs, CA to discuss several issues pending with the Nuclear Regulatory Commission (NRC) and the FDA. The key NRC issue dealt with responding to NRC’s Strategic Assessment Project. The ACNP/SNM previously suggested to the agency that it consider general licensing for diagnostic nuclear medicine and a workshop to discuss the regulatory requirements necessary for therapeutic nuclear medicine. The committee agreed with this approach and incorporated it into one of the committee goals for 1997.

The Committee, in one of its resolutions, passed the following goals for 1997:
1. NRC adoption of a general license for diagnostic and therapeutic nuclear medicine to eliminate unnecessary and inappropriate regulations.
2. Implementation by the FDA of a policy that allows fast track approval of diagnostic cancer agents.
3. Legislative reform of the FDA radiopharmaceutical approval process and other initiatives affecting nuclear medicine.
4. Monitoring of all government activities affecting nuclear medicine, providing updates and to respond when necessary.

The committee also discussed creation of a political action committee (PAC) to further its interests in Congress. SNM would sponsor the PAC and allow individual members to make contributions that would then be parcelled out to supporters of nuclear medicine in Congress. This idea was approved by both the government relations committee and the SNM Board of Directors.

The issue of presidential appointments was a lively topic of discussion, with both the FDA commissioner’s and the June, 1997 NRC commissioner’s positions appearing to be vacant. The committee discussed and approved support for Randy Juhl, PhD, Dean of the School of Pharmacy at the University of Pittsburgh for FDA commissioner. The committee also discussed the benefit of placing a nuclear medicine physician as Commissioner of the NRC and agreed to explore that option further. The next meeting of the government relations committee will be in San Antonio, TX during the SNM annual meeting.

ACNP/SNM Support Randy Juhl for FDA Commissioner

ACNP and SNM have recommended to Donna E. Shalala, Secretary of Health and Human Services, that she advise President Clinton to appoint Randy P. Juhl, PhD, to the position of FDA Commissioner. Juhl’s leadership qualities, management skills, academic reputation and experience serving the FDA and the public were cited in this recommendation. He has served as the first chair of the FDA’s Nonprescription Drugs Advisory Committee (NDAC), where he tackled issues related to the transfer of drugs from prescription to over-the-counter status, an area where the FDA had yet to engage its authority. As Dean of the School of Pharmacy at the University of Pittsburgh, he transformed a faltering program to one highly regarded nationally.

Commissioner David Kessler left the FDA at the end of February, and Deputy Director of Operations Michael Friedman will assume control as the lead deputy. A replacement commissioner is not expected to be confirmed by the Senate until September.

ACNP and SNM File a Petition for Stay of Action with FDA

ACNP/SNM have submitted a petition to the Dockets and Management Branch of the FDA to stay the effective date of FDA regulations governing PET. ACNP and SNM justified the stay because the FDA is unprepared to implement the regulation. Also, by granting a stay, the interests of justice will be served by preventing irreparable injury to the PET community, and the public interest will be served by protecting patients whose treatment is otherwise endangered. Granting a stay would remove an unfair legal cloud from the operation of PET centers and allow for continued high-quality medical care to patients. The ACNP and SNM are currently appealing a decision by the U.S. District Court regarding the process and legality of these PET regulations.

NRC Publishes Final Patient Release Criteria Rulemaking

The NRC has issued a final rule regarding the release of patients administered radioactive material. There has been a shift of focus to the potential dose to individuals who may come in contact with the patient. This rule is consistent with recommendations of the National Council on Radiation Protection and Measurements (NCRP) and the International Commission on Radiological Protection (ICRP). It will go into effect May 29, 1997. The following are the provisions of the rulemaking:
1. The licensee may authorize the release from its control of any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).

2. The licensee shall provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to others as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). If the dose to a breastfeeding infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breastfeeding, the instructions shall also include: (a) guidance on interruption of discontinuation of breastfeeding and (b) information on the consequences of failure to follow the guidance.

3. The licensee shall maintain a record of the basis for authorizing the release of an individual, for 3 years after the date of release, if the total effective dose equivalent is calculated by: (a) using the retained activity rather than the activity administered, (b) using an occupancy factor less than 0.25 at 1 meter, (c) using the biological or effective half-life or (d) considering the shielding by tissue.

4. The licensee shall maintain a record, for 3 years after the date of release, that instructions were provided to a breastfeeding woman if the radiation dose to the infant or child from continued breastfeeding could result in a total effective dose equivalent exceeding 5 mSv (0.5 rem).

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

---

**CHCPP News**

*Continued from page 20N*

ity patient care and service delivery. Many of these New York hospitals have a high number of IMGs, who now account for 40% of the residency slots filled each year. The project goal is to gradually decrease the dependence on IMG residents to provide essential service functions. Other recommendations of COGME include:

• Restructuring the current visa program for international medical graduates studying in the U.S. to return to their countries once training is complete.
• Allowing DME and IMEA payments in ambulatory care and other non-hospital settings as delivery patterns change in health care.

The proposed federal budget for this year contains significant cuts in Medicare spending which will undoubtedly affect the amount in payments made to teaching institutions. Most institutions have already made adjustments to their resident programs based on the changes occurring in the market. Many have decreased the number of resident positions to adjust for the downsizing of graduate medical education, or shifted the number of funded slots toward primary care training rather than medical specialty training.

COGME’s draft recommendations were approved in concept and will be sent out to its members for revision in the next few months. A final report will be submitted to the DHHS Secretary and Congress for review.

—Olivia Wong is the SNM health care policy administrator

---

**Newsbriefs**

**Reimbursement Roadshow Debut**

The SNM Commission on Health Care Policy and Practice (CHCPP) sponsored its first roadshow on reimbursement for nuclear medicine procedures on February 1 in Baltimore, MD. Forty-two participants attended the one-day seminar. Kenneth A. McKusick, MD, Darrell McIndoe, MD, and Denise Merlino, MBA, CNMT served as moderators. R. Thomas Loughery, MBA, a practice management consultant, was key speaker at the roadshow.

These workshops will cover major procedural aspects of nuclear medicine services, including proper code selection, claim submission and documentation. Nuclear medicine physicians, technologists, medical office managers, key billing and medical records personnel will learn how to properly use the current CPT and ICD-9-CM manuals, use HCPCS II for effective coding and billing, understand third-party payments, get updates on new editions of CPT and relevant Medicare changes, become knowledgeable about current Correct Coding Initiative, implications of fraud and abuse for incorrect coding, review common procedures and maximize reimbursement.

“These seminars focus on all the nuances of nuclear medicine. Physicians, technologists and coding and billing personnel will all benefit from the knowledge of these reimbursement roadshows,” said Wendy Smith, associate director of Health Care Policy.

The next reimbursement roadshow will be in conjunction with the SNM’s 44th Annual Meeting this June in San Antonio, TX. The categorical seminar will offer Category I CME and VOICE credit. Three additional roadshows will be offered this fall. For further information on upcoming roadshows contact Wendy Smith at (703) 708-9000, ext. 242 or via e-mail at wsmith@snm.org.

**DOE to Provide Research Isotopes**

The DOE will provide limited quantities of accelerator-produced isotopes for research purposes every month for two years beginning in October, 1997. Owen Lowe, associate director of DOE’s Office of Isotope Production and Distribution, stated that some funds will be available to subsidize the development and production costs. The isotopes will be produced in accelerators at the Brookhaven National Laboratory, Los Alamos National Laboratory and the Tri University Meson Facility. The DOE is developing criteria for establishing priorities for development and production. Suggestions concerning the criteria or interest in the isotopes may be addressed to Dr. Norton Haberman at 301-903-4321 or by e-mail to Norton.Haberman@hq.doe.gov.