Restoring Federal Commitment to Basic Nuclear Medicine Research

On September 20, the National Academy of Sciences released their State of the Science in Nuclear Medicine final report, *Advancing Nuclear Medicine Through Innovation*. One of the chief recommendations called for in the report is the enhancement of the federal commitment to nuclear medicine research through reinstating support for basic nuclear medicine research in the DOE Office of Science/Office of Biological and Environmental Research Medical Applications and Measurement Science (MAMS) program. This report verifies what we have known all along—federal funding of nuclear medicine research is extremely important.

See NAS Study Supports Enhanced Funding for Nuclear Medicine Research, page 14N, for more information on the NAS study, and visit the SNM Web site at www.snm.org/governmentrelations to see how you can help restore funding for basic nuclear medicine research at the DOE Office of Science.

PDUFA IV Signed by President Bush

On September 27, President George W. Bush signed the Prescription Drug User Fee Act (PDUFA) reauthorization legislation (HR 3580). The final compromise bill incorporated the House PET exemptions discussed in the July 2007 issue of the SNM/ACNP Health Policy and Regulatory Affairs newsletter, available online at http://interactive.snm.org/index.cfm?PageID=6678.

Section 103 of this legislation states that PET drug manufacturers will pay one-sixth of the annual establishment fee. In addition, it provides a special exemption from the annual establishment fee for not-for-profit medical centers with only one establishment for the production of PET drugs when at least 95 percent of the doses produced are used within the medical center.

Imaging Cuts in S-CHIP Reauthorization

In early October, the Senate stood firm in conference, and the House Medicare provisions that threatened to severely cut reimbursement for imaging services in 2010 as part of the proposed bill to reauthorize the State Children's Health Insurance Program (SCHIP) did not make it into the final bill. In addition, the President vetoed the legislation on October 3. However, it is probable that the House leadership will attempt to incorporate similar concepts into future Medicare-related legislation.

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NRC Publishes Final NARM Rule

The U.S. Nuclear Regulatory Commission (NRC) published the final rule on naturally occurring and accelerator-produced radioactive material (NARM) in the *Federal Register* on October 1. The final NARM rule was approved by the NRC on May 14 and was published after NRC rulemaking staff incorporated commission-directed changes to the text and obtained approval from the Office of Management and Budget for information-collection requirements.

The Energy Policy Act of 2005 expanded the definition of "byproduct material" subject to NRC authority to include discrete sources of radium-226, material made radioactive in a particle accelerator, and other radioactive material that the NRC determines could pose a threat to public health and safety or the common defense and security. The 34 Agreement States will continue to maintain authority over these materials under their agreements with the NRC.

The final NARM rule is effective November 30. In August 2005, the NRC issued a waiver allowing states to continue to regulate NARM while the NRC drafted regulations to implement the new requirements. The waiver is effective through August 7, 2009 (except for the import and export of NARM), unless terminated earlier by the NRC. At this writing, the NRC has determined that earlier termination of the waiver is warranted for persons owning, using, or otherwise engaging in activities involving NARM in the following states, territories, and settings: Delaware, Indiana, Wyoming, Montana, District of Columbia, Puerto Rico, U.S. Virgin Islands, federally recognized Indian tribes, and federal government agencies.

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