Senate FY 2006 NIBIB Appropriations Bill

On July 14, the Senate Appropriations Committee approved and sent to the floor the FY 2006 Departments of Labor, Health and Human Services, Education and Related Agencies bill. Contained within this legislation is the National Institutes of Health (NIH) National Institute of Biomedical Imaging and Bioengineering (NIBIB) appropriation, which is slated to rise only slightly over 2005 levels to $299.8 million. In the report accompanying the bill, the Senate Appropriations Committee made specific recommendations to NIBIB on urgent areas of research interest. These include: imaging and engineering advances in musculoskeletal disease detection, monitoring, and treatment; liver imaging techniques; and image-guided surgery. PET and microPET were singled out for special attention by the committee, who "continues to encourage the institute to devote significant resources to molecular imaging technologies such as PET and microPET to take advantage of the capacities of molecular imaging to detect disease process at the molecular level and to monitor the effectiveness of targeted gene therapies now under development." In addition, the committee also encouraged NIBIB to develop its research agenda "in close collaboration with other, disease-specific institutes at NIH, so that new imaging technologies are closely tied to the research projects being undertaken by the various other institutes of NIH."

United States Senate

Push for PET in Massachusetts

The *Boston Globe* reported on August 26 that Massachusetts hospitals are seeking to nearly double the number of PET and PET/CT scanners in the state, raising the number from 12 to 22. In response, national and regional health insurers have issued sharp warnings about possible effects on medical costs. "Our concern is that once a facility buys a very expensive piece of equipment, they are going to be pushing doctors to refer patients in order to pay for it," said Dr. Marylou Buyse, president of the Massachusetts Association of Health Plans.

The sudden demand for more PET units is the result of a 3-year moratorium imposed by the state Department of Public Health in 2002, after insurers expressed concerns when 8 new PET units were approved in a single year. New approvals are now being issued, with 4 scanners approved in August, 3 slated for September, and other applications expected to be filed. "There is pent-up demand—when it becomes the standard of care, it becomes harder to hold back the technology," said Ellen Zane, chief executive of Tufts–New England Medical Center, one of 4 hospitals with approved applications. Robert Licho, MD, director of nuclear medicine at the University of Massachusetts Memorial Medical Center in Worcester, told the *Globe* that, "This high-tech diagnostic information ultimately saves money because it directs correct medical decisions; it helps you carefully target therapies and avoid unnecessary surgery."

The Boston Globe

FDA Requests Nominations for Radiological Devices, Other Panels

The Food and Drug Administration (FDA) announced on August 24 a request for nominations for voting members to serve on the Radiological Devices Panel of the Medical Devices Advisory Committee (MDAC). Two openings for this panel must be filled starting on February 1, 2006.

The MDAC performs the following duties: (1) Advises the Commissioner of Food and Drugs on recommended classification or reclassification of devices into regulatory categories. (2) Advises on any possible risks to health associated with the use of devices. (3) Advises on formulation of product development protocols. (4) Reviews premarket approval applications for medical devices. (5) Reviews guidelines and guidance documents. (6) Recommends exemption of certain devices from the application of portions of the act. (7) Advises on the necessity to ban a device. (8) Responds to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices and may also make appropriate recommendations to the Commissioner on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

In addition to nominations for this panel, nominations are also being requested for voting members for certain device panels of the National Mammography Quality Assurance Advisory Committee, the Device Good Manufacturing Practice Advisory Committee, and the Technical Electronic Products Radiation Safety Standards Committee in the Center for Devices and Radiological Health. Any interested person may nominate 1 or more qualified persons for membership on the advisory panels or advisory committees. Self-nominations are also accepted. Nominations should include the complete curriculum vitae of each nominee, current business address and telephone number, and confirmation that the nomi-

nee is aware of the nomination, is willing to serve as a member, and appears to have no conflict of interest that would preclude membership.

Although no cutoff date is established for the receipt of nominations, the FDA requests nominations well in advance of the dates of scheduled vacancies. The full text of the announcement and contact information for the submission of nominations can be accessed in the August 24 *Federal Register* (*Fed Reg.* August 24, 2005;70:49656–49659).

Food and Drug Administration

Small Business Innovation Research Program

The Small Business Innovation Research (SBIR) program within the National Cancer Institute announced on August 9 that it is soliciting contract proposals from small businesses as well as research institution staff scientists who are serving as consultants to small business. The proposals are being sought on a number of research topics, including "Synthesis Modules for Radiopharmaceutical Production" and "Targetry Systems for Production of Research Radionuclides."

The SBIR program provides support for research and development (R&D) of new or improved technologies and methodologies that have the potential to succeed as commercial products. The SBIR legislation requires the Public Health Service, Department of Health and Human Services, and certain other federal agencies to reserve 2.5% of their extramural research or R&D budgets for SBIR programs. The date for receipt of contract proposals is November 4, and additional information on proposals can be accessed at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-060.html.

National Cancer Institute

NEMA Code of Ethics Changes

The National Electrical Manufacturers Association's (NEMA) announced on August 24 the publication of a new code of ethics for member companies that manufacture medical imaging and radiation therapy equipment. According to a NEMA press release, the code represents industry's desire to ensure adherence to the government's antikickback and false claim laws and to give guidance to NEMA member companies on how to interact with customers, including radiologists, cardiologists, nuclear medicine specialists, and orthopedists. It also provides assistance on handling entertainment, charitable contributions, grants, travel expenses for training, and other factors relating to or having influence on the procurement of the vendor's product. The new publication is consistent with revised general conflict of interest rules published by NEMA in January 2005 and is of special interest for the definitions and restrictions pertaining to industry support of product training and education, educational conferences, sales and promotional meetings, consulting arrangements, charitable donations, and research grants. Single copies of the new code may be available from representatives of member companies or can be ordered from Global Engineering Documents at www.global.ihs.com.

National Electrical Manufacturers Association

Penn Named DOD Breast Cancer Center of Excellence

The University of Pennsylvania School of Medicine has been named a Breast Cancer Center of Excellence by the Department of Defense Breast Cancer Research Program. This designation, which includes a 5-year, $10 million grant to SNM member Lewis A. Chodosh, MD, PhD, principal investigator and director of this Center of Excellence, establishes Penn as one of only 14 such sites in the United States. The Center represents a multidisciplinary approach to understanding breast cancer progression using state-of-the art noninvasive imaging techniques. Center researchers will employ a broad array of cellular and molecular imaging techniques to analyze a series of novel, genetically engineered models of breast cancer. The research team will use a comprehensive array of imaging technologies, including PET, MR, CT, MR spectroscopy, SPECT, and ultrasound, to visualize and follow tumor cells in living animals from their origins to their eventual progression to metastasis and recurrence. The Center of Excellence includes more than 2 dozen investigators at Penn, the University of California–Davis, Albert Einstein College of Medicine, McGill University, and the Children's Hospital of Philadelphia.

University of Pennsylvania

New ^{18}F-FDG NDA

On August 19, the Food and Drug Administration (FDA) approved a new drug application (NDA) for an ^{18}F-FDG injection. The NDA was submitted by Dr. Thomas Chaly from North Shore/LIJ Research Institute at the New York University Medical College (Manhasset). North Shore/LIJ Research Institute is the third institution in the United States to receive approval for the manufacture of an ^{18}F-FDG injection. The new NDA specification is for a strength of 20–200 mCi/mL, higher than the 2 previously approved NDAs. The ^{18}F-FDG is manufactured in a class 100,000 clean room environment and a class 100 biological cabinet for the preparation of the container closure vial.