Canada and Nonreactor ^{99m}Tc

The Canadian Isotope Project, led by Canadian Light Source (CLS; Saskatoon) and partners, including the National Research Council (NRC) of Canada and medical researchers in Winnipeg, Ottawa, and Toronto, announced on February 15 joint readiness to scale up ^{99}Mo production levels with the delivery of a new particle accelerator built by Ontario-based Mevex Corporation. "We are very excited to be passing this key milestone in the project," said Mark de Jong, CLS Director of Accelerators and project leader. "With the delivery of this full-scale accelerator we can now move to demonstrate what we set out to do—produce medical isotopes safely, reliably and affordably."

The Canadian Isotope Project uses a particle accelerator rather than a nuclear reactor to produce ^{99}Mo to ship for ^{99m}Tc production. According to a press release from CLS, 2 or 3 accelerator systems like that at CLS could supply all of Canada's current needs for ^{99m}Tc. Researchers at the NRC in Ottawa have been performing theoretical modeling of key aspects of the production process and producing small quantities of medical isotope using the same process that will be used at CLS. Isotopes produced by the full-scale facility at CLS will be chemically separated from the metal target by scientists at Health Sciences Centre (HSC) Winnipeg and assessed by physicians and physicists at the University of Ottawa Heart Institute and University Health Network in Toronto.

The Canadian Isotope Project was 1 of 4 projects funded by the government of Canada's Non-Nuclear Reactor Isotope Supply Programme (NISP). The project received $10 million from NISP, with an additional $2 million from the province of Saskatchewan. NISP was established to fund research into ways to produce medical isotopes without using a nuclear reactor, as a direct result of isotope shortages caused by difficulties with Canada's National Research University reactor. Installation of the accelerator at CLS was expected to be completed by the end of February, with the first experiments with the full-size accelerator system taking place in April. The first batch of radioisotopes is anticipated to be ready for shipment for testing at HSC Winnipeg by the end of April or early May.

Canadian Light Source

First Henkin Fellowship

SNM and the Education and Research Foundation of the SNM announced in February that Erin Grady, MD, of the Christiana Care Health System in Newark, DE, is the first recipient of the Robert E. Henkin Government Relations Fellowship. As part of the fellowship, Grady will come to Washington, DC, and spend a week at SNM headquarters, learning first-hand how the federal legislative and regulatory process affects nuclear medicine/molecular imaging. The new program is designed for young professionals, defined as residents or fellows (physicians, scientists, or technologists) who have completed their training within the last 10 y.

Grady is the immediate past president of the Nuclear Medicine Residents Organization and the current secretary/treasurer for the SNM Young Professionals Committee. She also serves as a director for the American College of Nuclear Medicine, is the outgoing resident member of the Nuclear Medicine Residency Review Committee at the Accreditation Council for Graduate Medical Education, and is the SNM Academic Council intern. She is actively participating in research on myocardial perfusion imaging, radioimmunotherapy, bone health, thyroid cancer, and methods to evaluate graduate medical education. In a recent role, she is leading SNM's effort on outreach to radiology benefit managers.

SNM

SNM Name Change

In January 2012 at the SNM Mid-Winter Meeting in Orlando, FL, the SNM House of Delegates (HOD), which includes the leadership of the society councils, centers, chapters, and technologist section, voted its support for a proposed SNM bylaw amendment that would change the society's name to the "Society of Nuclear Medicine and Molecular Imaging." The amendment passed the HOD by a greater than two-thirds majority. SNM members will vote to finalize the name change at the SNM annual business meeting on June 11, during the society's Annual Meeting in Miami, FL. For more information, see www.snm.org/namechange.

SNM

Medical Device User Fees Agreement

The U.S. Food and Drug Administration (FDA) and representatives from the medical device industry announced on February 1 that they had reached an "agreement in principle" on proposed recommendations for the third reauthorization of a medical device user fee program. The recommendations would authorize the FDA to collect $595 million in user fees over 5 y, plus adjustments for inflation. Details of the agreement, such as the fee structure, were expected to be finalized soon. Under a user fee program, industry agrees to pay fees to help fund a portion of the FDA's device review activities, and the FDA agrees to overall performance goals, such as reviewing a certain percentage of applications within a specified time frame.

The agreement in principle is the result of more than 1 y of negotiations between the FDA and was designed to result in such improvements as a more structured presubmission process and earlier interactions between FDA and applicants. With the additional funding, the FDA would be able to hire

more than 200 full-time equivalent workers by the end of the 5-y program. Both FDA and industry expect that the agreement in principle would result in a reduction in average total review times. Industry associations involved in the agreement include the Advanced Medical Technology Association, the Medical Device Manufacturers Association, and the Medical Imaging and Technology Alliance.

In September 2010, before beginning negotiations with regulated industry, the FDA held a public meeting on the device user fee program attended by stakeholders including industry, scientific and academic experts, health care professionals, and representatives from patient and consumer advocacy groups. Stakeholders provided their assessment of the overall performance of the program and their opinions about which aspects should be retained, changed, or discontinued to strengthen and improve the program. Once the final details of the agreement with industry are completed, FDA will develop a package of proposed recommendations and give the public an opportunity to comment before they are submitted to Congress.

U.S. Food and Drug Administration

DOE Labs Partnerships

On February 23, U.S. Department of Energy (DOE) Secretary Steven Chu announced that 8 of the DOE national laboratories will participate in a pilot initiative to make it easier for private companies to access the laboratories' research capabilities. Previously, companies wishing to partner with the laboratories for commercial research had 2 options: signing a Cooperative Research and Development Agreement (CRADA) or a Work For Others (WFO) Agreement. The 8 laboratories participating in this pilot program will now offer a third, more flexible option: an Agreement for Commercializing Technology (ACT). "The Agreements for Commercializing Technology will cut red tape for businesses and startups interested in working with our nation's crown jewels of innovation, the national laboratories," said Chu. "This initiative will also strengthen new domestic industries by helping to bring innovative, job-creating technologies to the market faster."

ACT innovations will include more flexibility in negotiating over intellectual property (IP) rights for technologies created at the laboratory. In the past, labs have had limited flexibility on IP terms under CRADAs and WFO arrangements. An ACT will allow both parties to develop a specialized arrangement that will facilitate moving the technology into the marketplace as quickly as possible. More flexible terms are also available on other issues ranging from payment arrangements to project structures to indemnification. An ACT will also make it easier to develop a multiparty research and development partnership. Groups of companies, universities, and/or other entities may come together with a laboratory to address complex technological challenges of mutual interest.

The participating labs are: Ames Laboratory, Brookhaven National Laboratory, Idaho National Laboratory, Lawrence Livermore National Laboratory, National Renewable Energy Laboratory, Oak Ridge National Laboratory, Pacific Northwest National Laboratory, and Savannah River National Laboratory. For more information, visit http://technologytransfer.energy.gov/ACTpilotFAQ.html.

U.S. Department of Energy

ICD-10 Compliance Postponed

U.S. Department of Health and Human Services (HHS) Secretary Kathleen G. Sebelius announced on February 16 that the department would initiate a process to postpone the date by which certain health care entities must comply with International Classification of Diseases, 10th Edition Diagnosis and Procedure Codes (ICD-10). Entities covered under the Health Insurance Portability and Accountability Act of 1996 will be required to use the ICD-10 diagnostic and procedure codes.

The final rule adopting ICD-10 as a standard was published in January 2009 and set a compliance date of October 1, 2013—a delay of 2 y from the original date initially specified in the proposed rule. HHS will announce a new compliance date in the near future. "ICD-10 codes are important to many positive improvements in our health care system," said Sebelius. "We have heard from many in the provider community who have concerns about the administrative burdens they face in the years ahead. We are committing to work with the provider community to reexamine the pace at which HHS and the nation implement these important improvements to our health care system."

U.S. Department of Health and Human Services

HIT and Proposed Stage 2 Rules

On February 22, Farzad Mostashari, MD, DSc, National Coordinator for Health Information Technology (HIT) announced proposed stage 2 rules on meaningful use of electronic health records. These rules, unlike those in stage 1, include imaging as a component. The announcement was made to attendees at the Healthcare Information and Management Systems Society meeting. The proposed stage 2 meaningful use requirements include viewing of images as an optional menu item, an announcement that met with mixed approbation and cautionary notes from the medical imaging community.

The stage 2 requirements will take effect in 2014. The stage 1 requirements remain in effect during 2013 and in the transition phase of 2014. CMS indicated that Stage 2 would keep the same core-menu structure for required measures. Physicians will meet 17 core objectives and 3 of 5 menu options. Hospitals will meet 16 core measures and 2 of 4 menu options. Physicians will report 12 clinical quality measures, and hospitals will report 24.

When the stage 2 rules were issued in draft in 2011, SNM submitted

a comment letter to Mostashari expressing concern about the absence of specific reference to access to medical images and reports through the electronic record. On February 24, SNM applauded the Office of the National Coordinator for HIT for recognizing the important role access to imaging plays in coordination of care.

Centers for Medicare & Medicaid Services

FROM THE LITERATURE

Each month the editor of Newsline selects articles on diagnostic, therapeutic, research, and practice issues from a range of international publications. Most selections come from outside the standard canon of nuclear medicine and radiology journals. These briefs are offered as a monthly window on the broad arena of medical and scientific endeavor in which nuclear medicine now plays an essential role. The lines between diagnosis and therapy are sometimes blurred, as radiolabels are increasingly used as adjuncts to therapy and/or as active agents in therapeutic regimens, and these shifting lines are reflected in the briefs presented here. We have also added a small section on noteworthy reviews of the literature.

Imaging Crohn Disease

In an article e-published on February 22 ahead of print in *Inflammatory Bowel Diseases*, Lenze et al. from the University of Muenster (Germany) reported on a study designed to determine the optimal noninvasive imaging method for detection of and differentiation between inflammatory and fibromatous stenoses in Crohn disease and to compare the results with those of endoscopic and histologic evaluation. The study included 37 patients with 37 strictures (22 inflamed, 12 mixed, and 3 fibromatous as classified by endoscopy and histology). Each patient underwent ^{18}F-FDG PET/CT, MR enteroclysis, and transabdominal ultrasound imaging. PET/CT and MR enteroclysis each detected 81% of strictures, and ultrasound detected 68%. MR enteroclysis was able to differentiate between inflammatory and fibromatous stenoses in 57% of strictures, with figures for PET/CT and ultrasound of 53% and 40%, respectively. Ultrasound, combined with either of the 2 other imaging techniques, was able to detect all strictures that required invasive treatment by surgery or endoscopic dilation therapy. The authors concluded that these results suggest a combination of these imaging approaches "as an alternative to endoscopy at least in the group of patients not able to perform an adequate bowel preparation."

Inflammatory Bowel Diseases

PET/CT and Tonsil SCC Therapy

Moon et al. from Sungkyunkwan University School of Medicine (Seoul, Republic of Korea) reported on February 6 ahead of print in *Head & Neck* on a study detailing the prognostic value of volume-based metabolic parameters as assessed by ^{18}F-FDG PET/CT in patients with squamous cell carcinoma of the tonsil. The study included 69 such patients who underwent PET/CT imaging before initiation of treatment. Parameters assessed were maximum standardized uptake value, metabolic tumor volume, total lesion glycolysis, and asymmetry indices of these 3 metrics. After adjusting for age, sex, and cancer stage, statistical analysis indicated that only total lesion glycolysis was an independent predictive factor in decreased overall survival.

Head & Neck

^{11}C-Mephobarbital PET at the BBB

In an article e-published on February 16 ahead of print in *Epilepsy Research*, Mairinger et al. from the Austrian Institute of Technology (Seibersdorf), the University of Vienna (Austria), and the Medical University of Vienna (Austria) reported on a study designed to determine whether the antiepileptic drug ^{11}C-mephobarbital is a substrate of P-glycoprotein (Pgp) and can be used with PET imaging to assess Pgp function at the blood–brain barrier (BBB). The study first assessed brain distribution of ^{11}C-mephobarbital in paired rats and mice before and after intravenous administration of the Pgp inhibitor tariquidar. The before and after scans were similar, suggesting that in vivo brain distribution of ^{11}C-mephobarbital is not influenced by Pgp efflux. This was confirmed in in vitro studies. Additional PET experiments in mice with and without pretreatment with multidrug resistance protein (MRP) inhibitor MK571 suggested that ^{11}C-mephobarbital is also not transported by MRPs at the murine BBB. This was also confirmed by in vitro transport experiments. The authors found these results to be surprising because "phenobarbital, the *N*-desmethyl derivative of mephobarbital, has been shown to be a substrate of Pgp, which suggests that *N*-methylation abolishes the Pgp affinity of barbiturates."

Epilepsy Research

PET Prediction in Soft Tissue Sarcomas

Herrmann et al. from the University of California Los Angeles reported on February 14 ahead of print in *Clinical Cancer Research* on a study designed to determine whether ^{18}F-FDG PET/CT after an initial cycle of neoadjuvant therapy can serve as an early intermediate endpoint biomarker of overall survival in patients with primary high-grade soft tissue sarcomas. The group had previously reported that PET identified treatment responders at the end of and after a single cycle of neoadjuvant therapy. The current study group included 57 patients who