ACGME Rescinds 2011 Minor Revision

In 2008 the Accreditation Council for Graduate Medical Education (ACGME) Diagnostic Radiology Residency Review Committee (RRC) decreased from 6 to 4 mo the amount of training radiology residents were required to take in nuclear medicine, while at the same time adding to the requirement for training in ^{131}I therapy with <33 mCi (for hyperthyroidism). Therapy training was not included in the diagnostic radiology requirements prior to 2008. Thus the Diagnostic Radiology RRC significantly increased the scope of practice of diagnostic radiology trainees at the same time that they decreased the amount of training. The nuclear medicine community did not respond to the 2008 revision. In July 2011, the ACGME Diagnostic Radiology RRC revised their residency training program requirements to include radiotherapy with >33 mCi ^{131}I (for thyroid cancer therapy). This was added as a minor revision, which avoided notification, review, or comment by potential stakeholders.

In November 2011, the American Board of Nuclear Medicine, American College of Nuclear Medicine, SNM, and the Nuclear Medicine RRC formally requested that the ACGME rescind this minor revision because it was in reality a major revision that requires stakeholder review and comments. The proposed program requirement significantly expanded the radiology scope of practice into cancer therapy without commensurate, adequate training. Given the already limited training of radiology residents in nuclear medicine and radiotherapy, this could affect patient care and patient safety. On March 6, 2012, the ACGME rescinded the new requirement. If the Diagnostic Radiology RRC decides to propose this as a major revision, it will be announced by the ACGME and comments will be solicited from stakeholders.

SNM

Cooperative Efforts on LEU

On March 26 President Barack Obama announced that the United States, Belgium, France, and The Netherlands had reached an agreement on sustaining the supply of clinical and research isotopes by phasing out the use of highly enriched uranium (HEU) and converting production and technology to low enriched uranium (LEU). The announcement was made in Seoul, Korea, during the second Nuclear Security Summit.

An accompanying White House press release noted that in some facilities, HEU is still needed to produce medical radioisotopes and that steady production of radioisotopes has been challenged by a series of shutdowns and other crises. Belgium, France, and The Netherlands, as the leading European countries involved in producing isotopes, have already shown their ability to find solutions for temporary shortages by prompt redirection of medical radioisotope production during recent supply crises. The United States continues to explore alternatives. The agreement reaffirmed the 4 countries' commitment to support conversion of European production industries to non-HEU-based processes by 2015, with similar conversion in the United States. At the same time, with the objective of HEU minimization and with a view to an overall effective decrease of existing HEU, Belgium, France, and The Netherlands "will deal in a responsible manner with existing large amounts of scrap HEU resulting from past activities by recycling or disposing them, with the support of the United States and other partners."

The United States expressed willingness to supply the 3 partner countries during the transition period with the necessary HEU target material to ensure uninterrupted production of medical isotopes urgently needed for diagnosing heart disease, cancer, and studying organ structure and function, while achieving the goal of HEU minimization. Additional agreements on HEU minimization were reached with South Korea. "Simply put, we are reducing the availability of highly enriched uranium, a weapons-grade material, and [this] reduces the chances of the material flowing to the wrong hands," U.S. Energy Secretary Steven Chu said at a related press conference. Several news sources pointed out the absence of Canada as a partner in this cooperative agreement.

The White House

Structure, Function, and Williams Syndrome

In an article published on March 12 ahead of print in the *Proceedings of the National Academy of Sciences of the USA* and widely covered in the national media, Jabbi et al. from the National Institutes of Health (NIH; Bethesda, MD) described a study using multimodality brain imaging to identify distinct structural and functional features in individuals with Williams syndrome. This genetic disorder is most often accompanied by hypersocial activity and anxious personality, among other traits. The disorder is caused by the deletion of 28 genes in a segment of chromosome 7, many of which are involved in brain development and behavior. Fourteen intellectually normal Williams syndrome participants and 23 healthy controls underwent multimodal imaging (PET, MR, and MR diffusion tensor imaging [DTI]) to characterize the insula, with the hypothesis that the area's anatomy, function, and connectivity would predict patients' scores on Williams syndrome–associated traits on personality rating scales. MR results showed decreased gray matter in the insula, DTI showed reduced white matter in the area, and PET both confirmed the findings and identified altered functional coupling between the front of the insula and key structures involved in thinking, mood, and fear processing. These structural and functional abnor-

malities correlated well with patients' results on the personality assessment instrument. "Our findings illustrate how brain systems translate genetic vulnerability into behavioral traits," said Karen Berman, MD, senior author of the study, in an NIH press release. The authors concluded that, "The anterior insula's rich anatomical connectivity, its transmodal properties, and its involvement in the behaviors affected in Williams syndrome make the observed genetically determined insular circuitry perturbations and their association with Williams syndrome personality a striking demonstration of the means by which neural systems can serve as the interface between genetic variability and alterations in complex behavioral traits."

Proceedings of the National Academy of Sciences of the USA

Public/Private Resource for Drug Development

On March 13, the National Institutes of Health (NIH) and Eli Lilly and Company announced plans to generate a publicly available resource to profile the effects of thousands of approved and investigational medicines in a variety of sophisticated disease-relevant testing systems. Through the collaboration, the NIH's newly established National Center for Advancing Translational Sciences (NCATS) and Lilly Research Laboratories have agreed that NCATS' Pharmaceutical Collection of 3,800 approved and investigational medicines will be screened using Lilly's state-of-the-art Phenotypic Drug Discovery (PD2) panel. This panel features assays designed to reveal novel mechanisms or pathways of potential medicines and, as part of this collaboration, approved medicines as well. As such, the panel may provide new insights for drug discovery.

"This innovative collaboration with Lilly is exactly the type of partnership that NCATS is eager to foster with many other groups from industry, government, and academia," said NCATS Acting Director Thomas R. Insel, MD. "Working together, we can make drug development pipelines more productive. The key is precompetitive collaboration to benefit all partners, ensuring broad access to the results."

The NCATS Pharmaceutical Collection is a comprehensive publicly available database (http://tripod.nih.gov/npc) and is a physical sample collection. The PD2 assay panel, part of Lilly's Open Innovation Drug Discovery platform (https://openinnovation.lilly.com), includes sophisticated human disease pathway–related assays relevant to cardiovascular diseases, cancer, and endocrine disorders, among others. These testing systems are designed to reveal novel mechanisms or pathway activities of drugs.

Screening will take place over the next 12 to 18 mo, and results will be made freely available on the NCATS database. For example, if an approved medicine is found to be a possible treatment candidate for a new disease indication, a partnership with the organization that owns the chemical compound could be formed to pursue additional studies. These might include clinical trials required for marketing approval by the U.S. Food and Drug Administration. In another approach, medicines with activity in the PD2 assays might serve as starting points for additional chemistry research efforts to produce new medicines.

National Center for Advancing Translational Sciences

NIH Online Genetic Test Resource

The National Institutes of Health (NIH) announced on February 29 the launch of an online tool, the Genetic Testing Registry (GTR), designed to simplify both consumer and research navigation through the rapidly changing landscape of genetic tests. Genetic tests currently exist for about 2,500 diseases, with more added almost daily. The GTR will be updated frequently, using data voluntarily submitted by genetic test providers. Such information will include the purpose of each genetic test and its limitations, name and location of the test provider, whether it is a clinical or research test, what methods are used, and what is measured. Although genetic tests that the Food and Drug Administration (FDA) has cleared or approved as safe and effective are identified in the GTR, most laboratory-developed tests currently do not require FDA premarket review. Genetic test providers will be solely responsible for the content and quality of the data submitted to the GTR. In addition to basic facts, the GTR will offer detailed information on analytic validity, clinical validity, and data relating to the test's clinical utility. The database also offers context-specific links to practice guidelines and a variety of genetic, scientific, and literature resources available through the National Library of Medicine (NLM). The GTR database was developed by the National Center for Biotechnology Information, part of NLM, under the oversight of the NIH Office of the Director and with extensive input from researchers, testing labs, health care providers, patients, and other stakeholders. "I'm delighted that NIH has created this powerful, new tool. It is a tremendous resource for all who are struggling to make sense of the complex world of genetic testing," said NIH Director Francis S. Collins, MD, PhD, who unveiled GTR at NIH's observance of international Rare Disease Day. "This registry will help a lot of people—from health care professionals looking for answers to their patients' diseases to researchers seeking to identify gaps in scientific knowledge." Video tutorials are available at: www.youtube.com/playlist?list=PL1C4A2AFF811F6F0B. The GTR is available at www.ncbi.nlm.nih.gov/gtr/.

National Institutes of Health

SNM and PCORI Draft

On March 13, SNM provided comments on the Patient-Centered Outcomes Research Institute (PCORI) Draft National Priorities and Research Agenda. PCORI is an independent, nonprofit health research organization focusing on funding comparative clinical effectiveness studies that offer "patients and caregivers the information they need to make important healthcare decisions." PCORI focuses on "comparative clinical effectiveness" research. On January 23

PCORI released its draft priorities in: (1) assessment of prevention, diagnosis, and treatment options; (2) improving health care systems; (3) communication and dissemination; (4) addressing disparities; and (5) accelerating patient-centered and methodologic research. Comments from the public and medical professionals were solicited.

In its comment letter, SNM encouraged PCORI to further engage smaller medical specialty societies that may lack resources to develop competitive proposals for comparative effectiveness research funding, but whose members are uniquely qualified to design and conduct such studies. In addition, SNM recommended that PCORI use changes in treatment decisions as one type of endpoint in studies and that it incorporate separate methodologies for therapeutic and diagnostics into its research designs and those conducted by other groups.

SNM

International Workshop on Interim PET

An article appearing on March 20 ahead of print in *Leukemia and Lymphoma* provided an overview of and report on consensus findings from the Third International Workshop on Interim PET in Lymphoma, held in Menton, France, September 26 and 27, 2011. The 2-d meeting was attended by 193 hemato-oncologists and nuclear medicine specialists from 23 countries. In the summary article, Meignan et al. reported on final results of international validation studies of the Deauville criteria and ΔSUV_{max} analyses in Hodgkin lymphoma (HL) and non-Hodgkin lymphoma (NHL). These studies confirmed the prognostic value of interim PET in 261 patients with advanced HL after 2 cycles of adreomycin, bleomycin, vinblastine, and dacarazine when reported with a 5-point scale and in 120 patients with diffuse large B-cell lymphoma after 2 cycles of a rituximab-based immunochemotherapy regimen when using the ΔSUV analysis. At the meeting, a preliminary consensus on interim PET was established on assessment of marrow response, refining of grade 4 and 5 of the 5-point scale, the need to focus on interim PET results for different types of NHL, and methods to compute and factors affecting measurement of SUV change. The next meeting, scheduled for October 2012, will include aspects of PET in lymphoma beyond interim PET findings. The 2011 presentations are available on http://eitti.free.fr.

Leukemia and Lymphoma

NRC Proposed Fee Schedule

On March 15, the Nuclear Regulatory Commission (NRC) released the proposed FY 2012 fee schedule, detailing licensing, inspection, and annual fees charged to its applicants and licensees. Included is an estimated fee-relief budget of $91.1 million, which NRC proposes to use to decrease all licensees' annual fees based on their percentage share of the fee-recoverable budget authority. The fee relief budget is higher than FY 2011 because of decreased international activities and educational budgets. The NRC has included medical isotope production under fee relief categories to capture program activity for medical isotope production facilities for regulatory basis development. The FY 2012 NRC medical isotope budget of approximately $3 million is not attributable to existing NRC licensees. The funding for this activity along with other activities not attributable to existing NRC licensees will be offset by the agency's 10% appropriation. The entire fee schedule announcement is available at: www.gpo.gov/fdsys/pkg/FR-2012-03-15/html/2012-6153.htm.

Nuclear Regulatory Commission

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.

4D PET/CT + MR in Radiotherapy

Bundschuh et al. from the Technischen Universität München (Germany) reported on March 24 ahead of print in *Strahlentherapie und Onkologie* on a study of the utility of 4D ^{18}F-FDG PET/CT in combination with respiratory gated MR imaging for target volume definition in stereotactic radiation of liver metastases. The study included 18 patients scheduled for radiation therapy who underwent respiration-gated PET/CT and MR imaging. Resulting data were coregistered, and the quality of coregistration was rated on a 1 to 5 (excellent to poor) scale, including both gated and nongated PET results. Three imaging experts delineated gross tumor volumes (GTVs) for each modality, and interobserver variability was calculated for the entire group of patients and for subgroups with and without previous