FDA Drug Shortage App

The U.S. Food and Drug Administration (FDA) announced on March 4 the launch of the agency's first mobile application (app) specifically designed to speed public access to information about drug shortages. The app identifies current drug shortages, resolved shortages, and discontinuations of drug products. "The FDA understands that health care professionals and pharmacists need real-time information about drug shortages to make treatment decisions," said Valerie Jensen, RPh, associate director of the Drug Shortage Staff in the FDA Center for Drug Evaluation and Research. "The new mobile app is an innovative tool that will offer easier and faster access to important drug shortage information." App users can search or browse by a drug's generic name, active ingredient, or therapeutic category. The app can also be used to report a suspected drug shortage or supply issue to the FDA. The agency developed the app to improve access to information about drug shortages, as part of FDA efforts outlined in the recent Strategic Plan for Preventing and Mitigating Drug Shortages. The app is available for free download via iTunes and the Google Play stores by searching "FDA Drug Shortages."

U.S. Food and Drug Administration

2015 Henkin Fellows Named

David Douglas, MD

SNMMI and the Education and Research Foundation for Nuclear Medicine and Molecular Imaging announced on February 26 that David Douglas, MD, and Benjamin Franc, MD, had been named as recipients of 2015 Robert E. Henkin Fellowships. Each year, recipients of the award travel to Washington, DC, to spend a week with SNMMI staff visiting Congress, federal agencies, and other medical societies. Throughout the week, the fellows learn about the ways in which federal legislative and regulatory processes affect nuclear medicine and molecular imaging. The program is designed for young professionals, defined as residents or fellows (physicians, scientists, or technologists) who have completed their training within the last 10 years. These fellowships were made possible by a generous donation from Robert E. Henkin, MD.

Benjamin Franc, MD

Douglas is currently completing a fellowship at the Stanford University School of Medicine (CA), training in nuclear medicine and neuroradiology. At the University of California, Davis, while completing his residency, he performed >300 interventional radiology procedures and received the Goldberg–Reeder Award, which provides a stipend for qualified residents seeking to spend at least 1 month assisting in health care activities in a developing country.

Franc is a professor of radiology at the University of California, San Francisco. He previously worked at Sutter Health and the Radiological Associations of Sacramento Medical Group. He serves on SNMMI's Coding & Reimbursement Committee, on the Legislative Committee of the California Medical Association, and on the California Contractor Advisory Committee for the Centers for Medicare & Medicaid Services.

SNMMI

Invasive Cancer Survival Rates Improve

A study published by the Centers for Disease Control and Prevention (CDC) in its *Morbidity and Mortality Weekly Report* on March 12 indicated that 2 of 3 individuals diagnosed with invasive cancer today will survive 5 or more years. The report found that the most common cancer sites continue to be cancers of the prostate (128 cases per 100,000 men), female breast (122 cases per 100,000 women), lung and bronchus (61 cases per 100,000 persons), and colon and rectum (40 cases per 100,000 persons). For these common cancer sites, 5-y relative survival was 97% for prostate cancer, 88% for breast cancer, 63% for colorectal cancer, and 18% for lung cancer. "We are pleased to include cancer survivor data in this report for the first time. We will review these data annually to track our progress," said Jane Henley, MSPH, an epidemiologist in CDC's Division of Cancer Prevention and Control and lead author of the study.

The cancer survivor estimates are from CDC's National Program of Cancer Registries. CDC scientists reviewed the most recent data on cases of invasive cancers reported during 2011. With the exception of urinary bladder cancer, invasive cancer is defined as cancer that has spread to normal tissue outside of the area in which it began. The authors noted that disparities in cancer incidence still persist, with greater rates among men than women and the highest rates among African Americans. In addition, 5-y relative survival after any cancer diagnosis was lower for African Americans (60%) than for whites (65%).

Individual state data in the report indicated that incidence rates for all cancer sites vary widely, ranging from 374 cases per 100,000 persons in New Mexico to 509 cases per 100,000 persons in the District of Columbia. "These data are an important reminder that a key to surviving with cancer is making sure everyone has access to care from early diagnosis to treatment," said Lisa Richardson, MD, director of the CDC Division of Cancer Prevention and Control. "We know, for example, that early detection of colorectal cancer has had the largest impact on long-term survival rates." The full report, "Invasive Cancer Incidence and

Survival—United States, 2011," can be found at www.cdc.gov/mmwr.

Centers for Disease Control and Prevention

Ending Data Collection for NaF-18 PET

On March 16, the Centers for Medicare & Medicaid Services (CMS) solicited public comment on ending prospective data collection requirements through the National Oncologic PET Registry (NOPR) and coverage with evidence development (CED) for use of NaF-18 PET imaging in intended patient management. In a letter dated February 5, NOPR leaders presented analyses of additional registry data supporting their request for an end to the data collection requirement and immediate authorization of national coverage of NaF PET imaging for bone metastases in all oncologic indications. The letter, signed by Bruce E. Hillner, MD, NOPR chair, Barry A. Siegel, MD, NOPR cochair, and Anthony F. Shields, MD, NOPR cochair, was a request for reconsideration following a May 14, 2014, letter urging an end to CED and approval of NaF-18 PET in bone metastasis. The authors noted: "...we strongly believe that the purpose of CED for NaF PET for bone metastasis has been fulfilled, as the NOPR has now demonstrated through its published research of the CED evidence that NaF PET is both reasonable and necessary in this regard. In light of the extensive NOPR data collection on NaF PET since 2011, including newly published data in the *Journal of Nuclear Medicine*, we are convinced that there remains no clinical need to continue CED data collection for NaF PET for bone metastasis." The new data appeared in "^{18}F fluoride PET used for treatment monitoring of systemic cancer therapy: results from the National Oncologic PET Registry," in the February issue of the journal (*J Nucl Med.* 2015;56:222–228). The complete letter and associated data are available at: http://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id279.pdf. The deadline for public comments to CMS was April 15, 2015. A CMS decision is anticipated in the near future.

Centers for Medicare & Medicaid Services

Joint IT Interoperability Rules Proposed

The U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) and Office of the National Coordinator for Health Information Technology (ONC) announced on March 20 the release of the Stage 3 notice of proposed rulemaking for the Medicare and Medicaid Electronic Health Records (EHRs) Incentive Programs and 2015 Edition Health IT Certification Criteria to address the ways in which electronic health information is shared. The agencies indicated that the proposed rules are designed to give health care providers additional flexibility, simplify the program, drive interoperability among EHRs, and increase foci on patient outcomes to improve care.

The Meaningful Use Stage 3 proposed rule issued by CMS specifies new criteria that eligible professionals, eligible hospitals, and critical access hospitals must meet to qualify for Medicaid EHR incentive payments. The rule also proposes criteria that providers must meet to avoid Medicare payment adjustments based on program performance beginning in payment year 2018. The rule gives more flexibility and simplifies requirements for providers by focusing on advanced use of EHRs and elimination of outdated requirements.

The 2015 Edition Health IT Certification Criteria proposed rule aligns with the strategies identified in ONC's draft shared Nationwide Interoperability Roadmap. "This Stage 3 proposed rule does three things: it helps simplify the meaningful use program, advances the use of health IT toward our vision for improving health delivery, and further aligns the program with other quality and value programs," said Patrick Conway, MD, MSc, CMS acting principal deputy administrator and chief medical officer. "And, in an effort to make reporting easier for health care providers, we will be proposing a new meaningful use reporting deadline soon."

Under the Health Information Technology for Economic and Clinical Health Act, doctors, health care professionals, and hospitals, including critical access hospitals, can qualify for Medicare and Medicaid incentive payments when they adopt and "meaningfully use" health IT technology certified by ONC. Since the programs began in 2011, more than 433,000 eligible professionals and hospitals have received an incentive payment, including about 60% of eligible professionals in either the Medicare or Medicaid programs and about 95% of eligible hospitals. The Stage 3 proposed rule's scope is generally limited to requirements and criteria for meaningful use in 2017 and subsequent years. CMS is considering additional changes to meaningful use beginning in 2015 through separate rulemaking.

Comments on both the Stage 3 proposed rule and the 2015 Edition proposed rules are due by May 29. These rules may be viewed at https://www.federalregister.gov/articles/2015/03/30/2015-06685/medicare-and-medicaid-programs-electronic-health-record-incentive-program-stage-3 and https://www.federalregister.gov/articles/2015/03/30/2015-06612/health-information-technology-certification-criteria-base-electronic-health-record-definition-.The Draft 2015 Edition Certification Test Procedures may be viewed at https://confluence.oncprojectracking.org/display/CERTTEST2015/ONC+Health+IT+Certification+Program+2015+Edition+Test+Methods+Home, and the comment period ends on June 30.

U.S. Department of Health and Human Services

SNMMI Comments on Proposed Tech CT Qualifications

On March 9, SNMMI submitted comments and proposed new language in a letter to The Joint Commission about technologist qualifications necessary to perform diagnostic CT exams that are not

a part of a fusion or hybrid modality imaging study. SNMMI worked with the American Registry of Radiologic Technologists (ARRT), American Society of Radiologic Technologists, and the Nuclear Medicine Technology Certification Board (NMTCB) to formulate and propose new language that establishes and clarifies the qualifications needed for nuclear medicine technologists who perform standalone diagnostic CT exams. The comments letter, signed by April Mann, MBA, CNMT, NCT, RT(N), president of the SNMMI Technologist Section, included 3 recommended alternative standards for individuals who perform these exams. These include certification and registration in CT by the ARRT or active certification in CT by the NMTCB. A third alternative "grandfathering provision" would apply to those individuals with "no eligibility pathway to earning CT certification due to not having graduated from an accredited educational program in radiography, nuclear medicine technology, or radiation therapy" and would require specific documentation and standards to be supplied by the employing hospital. The letter also contained suggested steps for clarifying language on technologist certification. The complete text of the letter is available at: http://www.snmmi.org/files/FileDownloads/SNMMI%20Letter%20to%20The%20Joint%20Commission%20-%203-9-2015_FINAL.pdf.

SNMMI

Varmus Steps Down at NCI

The National Institutes of Health (NIH) announced on March 4 that Harold Varmus, MD, who had led the National Cancer Institute (NCI) for almost 5 would step down from his post as director, effective March 31. "It has been our great fortune to have Harold at the helm of the NCI," said NIH Director Francis S. Collins, MD, PhD. "His breadth and depth of expertise in biomedical research is unparalleled, and he's been a tremendous colleague to me and invaluable to the agency." Douglas Lowy, MD, who previously served as NCI deputy director, became acting director on April 1. He is a long-time NCI intramural researcher and received the National Medal of Technology and Innovation in 2014 for his research leading to development of the human papillomavirus vaccine.

As NCI director, Varmus instituted the Provocative Questions initiative, created NCI's new Center for Global Health, revitalized the cooperative clinical trials system, launched an initiative to identify drugs that target the cell signaling pathway controlled by the RAS oncogene, led the cancer component of the Precision Medicine Initiative, and continued to make contributions to biomedical research. Varmus has maintained a long-standing association with NIH, dating back to 1968, when, as a young Public Health Service officer, he studied bacterial gene expression with Ira Pastan, MD, currently chief of NCI's Laboratory of Molecular Biology.

For more information, including Varmus's letter to NCI staff, see: http://www.cancer.gov/aboutnci/director/messages/harold-varmus-resignation.

National Institutes of Health

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.

PET/CT in Multiple Myeloma Treatment

In an article e-published on March 6 ahead of print in *Biology of Blood and Marrow Transplantation*, Patriarca et al. from the University of Udine (Italy) and a consortium of researchers from 6 other Italian research centers reported on the ability of ^{18}F-FDG PET/CT to provide prognostic information and monitor treatment in patients with multiple myeloma undergoing allogeneic stem cell transplantation. The study included 54 patients after upfront autologous stem cell transplantation who underwent PET/CT before and/or 6 mo after allogeneic transplantation, either as consolidation or salvage treatment. Twenty-two patients (41%) had negative imaging results at transplantation, 11 (20%) had 1–3 focal lesions, and 21 (39%) had either diffuse bone marrow involvement or >3 focal lesions. Extramedullary disease was seen in 6 patients (11%) and maximum standardized uptake value (SUV) was >4.2 in 21 (39%). Analysis of results showed that persistence of extramedullary disease at allogeneic transplantation was an independent predictor of poor progression-free survival and that SUV > 4.2 and unrelated donor status were factors that negatively affected overall survival. For posttransplant imaging, persistence of extramedullary disease and failure to reach a complete or very good partial response were associated with shorter progression-free and overall survival. Forty-six patients