Douglas and Franc Chosen as Recipients of the 2015 Henkin Fellowship

SNMMI and the Education and Research Foundation for Nuclear Medicine and Molecular Imaging are pleased to announce that David Douglas, MD, and Benjamin Franc, MD, are the recipients of the 2015 Robert E. Henkin Fellowship. Each year, the recipients come to Washington, DC, and spend a week with SNMMI staff visiting Congress, federal agencies and other medical societies. Throughout the week, the Fellows learn, first-hand, how the federal legislative and regulatory process impacts nuclear medicine/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).

Dr. Douglas is currently completing a fellowship at the Stanford University School of Medicine, training in Nuclear Medicine and Neuroradiology. Previously, he spent six years at the University of California, Davis, where, while completing his residency, he performed more than 300 interventional radiology procedures and received the Goldberg-Reeder Award, which provides a stipend for qualified residents seeking to spend at least one month assisting health care in a developing country.

Dr. Franc currently serves as 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. Dr. Franc currently serves on SNMMI’s Coding & Reimbursement Committee, on the Legislative Committee of the California Medical Association, and on the California Contractor Advisory Committee for CMS.

This fellowship would not be possible without the generous contributions made by Dr. Robert E. Henkin. Dr. Henkin’s hard work and dedication to nuclear medicine and molecular imaging have been invaluable to SNMMI.

FDA Releases Compounding Guidance

On Friday, February 13, the U.S. Food and Drug Administration (FDA) released four draft guidances, including a draft Memorandum of Understanding (MOU) related to sterile drug compounding. Two of the guidances are related to Section 503B on outsourcing facilities. The other two pertain to both Section 503A (pharmacies) and 503B (outsourcing facilities) and address repackaging of certain human drugs and biologics. The draft guidances are necessary to establish the conditions that must be met in order for repackaging to be exempt from FDA enforcement action. The documents also address hospital and health system repackaging of drugs that are on FDA’s drug shortage list.
Currently, radiopharmaceutical compounding is not addressed in any statute, regulation or FDA guidance, except for the 1984 Nuclear Pharmacy Guideline which is brief. Radiopharmaceuticals were exempted from the 503A regulations in the recently enacted Drug Quality and Security Act. The FDA is currently working on draft guidance specifically for radiopharmaceuticals. The draft guidances released on February 13 provide a glimpse into possible implications for radiopharmaceutical compounding. SNMMI believes there is a need for public guidance on how the FDA will exercise enforcement discretion of radiopharmaceutical compounding.

The FDA also released a draft MOU, which would establish an agreement between states and FDA about interstate distribution of compounded drug products. The draft MOU defines the phrase “inordinate amounts” as it relates to compounded products that can be distributed interstate. Specifically, the draft MOU defines “inordinate amounts” as “an amount of compounded drug product distributed interstate in a given month that is equal or greater to 30% of all drug products dispensed or distributed by the pharmacist, pharmacy, or physician.” The draft MOU requires states to report distribution of “inordinate amounts” of compounded drug products to FDA. The MOU also does not include an exemption for border states, such as New York and New Jersey, to distribute compounded drug products, nor does it include safeguards for drug shortages.

How the FDA defines “radiopharmaceutical compounding” and “radiopharmaceutical preparation” will become very important in our guidance. SNMMI defines “radiopharmaceutical preparation” to mean either activities performed in accordance with the instructions in the FDA-approved labeling, or minor deviations from those instructions.

The Society of Nuclear Medicine and Molecular Imaging previously submitted comments on compounding in September 2014 and again in November 2014 with several specialty societies. The Society is planning to submit comments again and will reiterate that nuclear pharmacies play a distinct and vital role in the preparation and distribution of radiopharmaceutical products and should be given adequate consideration in the policymaking process. Nuclear pharmacies are an essential link in patient care, as they provide patient-specific unit dose radiopharmaceutical products to hospitals and clinics throughout the U.S.

The guidances have a 90-day comment period, and the draft MOU has a 120-day comment period. Comments may be submitted electronically at regulations.gov. The society will share our public comments once finalized.

FDA Releases Guidance on Clinical Trial Imaging Endpoints

On Thursday March 5th, the FDA released a new guidance document, "Clinical Trial Imaging Endpoint Process Standards." The new document revises the draft guidance for industry, "Standards for Clinical Trial Imaging Endpoints," which was released in August 2011. The guidance focuses on imaging acquisition, display, archiving and interpretation process standards. The FDA intends for the document to support the approval of drug and biological products. However, the document does exclude specific imaging measures and whether or not specific measures would be acceptable in submissions used to support approval of a drug or a biologic. FDA believes that several of the imaging process standard considerations for clinical trials of therapeutic drugs can also be applied to clinical trials that evaluate the performance of diagnostic drugs. Comments on the draft guidance document are due May 5, and can be submitted at regulations.gov.

SNMMI Submits Comments to CMS Regarding APC Remodeling

On February 13, 2015, the Society of Nuclear Medicine and Molecular Imaging (SNMMI) submitted comments to the Centers for Medicare and Medicaid Services, accompanied by data and reconfiguration options. SNMMI hopes to have these proposed edits incorporated into the Calendar Year (CY) 2016 Hospital Outpatient Prospective Payment System (HOPPS) proposed rule.

SNMMI is concerned with diagnostic (Dx) radiopharmaceutical (Rp) costs and the current HOPPS ambulatory payment classification (APC) structure. These costs can hinder the use or adoption of nuclear medicine procedures and their Dx Rps. There is also concern for patients, as some hospitals have stopped performing services, forcing them to go elsewhere for testing. Additionally, we are worried for future innovation and sustained products due to companies exiting the nuclear medicine market in recent years. In an effort to provide CMS with an option that incorporates packaging as a principle, SNMMI proposed that CMS should create separate Rp APCs in combinations with the new nuclear medicine APC procedure structure.
SNMMI Weighs In

SNMMI provides comments to government stakeholders on a multitude of issues. For more information, please visit the SNMMI website or contact the HPRA department directly.

- On Friday, December 19, 2014, SNMMI submitted comments to CMS regarding the CY15 HOPPS Final Rule.
- On Tuesday, December 23, 2014, SNMMI submitted comments to CMS regarding the CY15 MPFS Final Rule.
- On Friday, January 26, 2015, SNMMI submitted comments to the DEA regarding their regulation of DaTscan™.

Upcoming Events/Deadlines

- The Nuclear Regulatory Commission (NRC) Advisory Committee on the Medical Use of Isotopes (ACMUI) meeting will take place March 19-20, 2015.
- Capitol Hill Day will be April 27, 2015. If you are interested in participating, please contact Jesse Schoolnik at jschoolnik@snmmi.org.

Contact hpra@snmmi.org to be notified by email of future newsletters.