2015 Robert E. Henkin Government Relations Fellowship

Dr. Robert E. Henkin, SNMMI and the Education and Research Foundation hosted the 2015 Robert E. Henkin Fellows, David Douglas, MD, from the Stanford University School of Medicine in Stanford, CA, and Ben Franc, MD, from the University of California in San Francisco, CA.

The fellows spent a week in Washington, DC, and gained firsthand knowledge of Capitol Hill and inside federal agencies. During their whirlwind week, the pair met with officials from Congress; the Food and Drug Administration; the Centers for Medicare and Medicaid Services; the National Institute of Biomedical Imaging and Bioengineering; the National Cancer Institute; the Nuclear Regulatory Commission; the National Nuclear Security Administration; the Office of Science and Technology Policy; and several medical societies and trade associations. Topics discussed included domestic isotope production of Molybdenum-99 (Mo-99), Medicare reimbursement, the approval pathway at FDA, research grant funding, appropriate use criteria, and other issues.

Applications for the 2016 Fellowship will be accepted from September 1 - December 31, 2015. The new Fellows will be selected at the SNMMI Mid-Winter Meeting with the fellowship week to occur at a time mutually agreed upon between February and May 31, 2016.

SNMMI Holds Annual Capitol Hill Day

SNMMI recently held its annual Capitol Hill Day on Monday, April 27, 2015. This year there were 45 participants who met with 62 congressional offices representing 20 states. The following are the main topics that were discussed:

1. A Reliable Domestic Supply of Molybdenum-99 (Mo-99): While the United States uses 50 percent of the world’s Mo-99, our supply primarily comes from reactors in other countries, primarily Canada and the Netherlands. However, the Canadian facility will be phased out of commercial isotope production beginning in 2016 with standby capability until 2018. Additionally, in 2012, Congress enacted the American Medical Isotopes Production Act (AMIPA) of 2011, which requires industry to convert its technology from highly enriched uranium (HEU) to non-Highly Enriched.

Left to right: Gary Diellehay, MD; Erica Cohen, DO; Tina Buehner, CNMT; and Nancy McDonald, CNMT
2. **Appropriate Reimbursement for Radiopharmaceuticals**: Every year, millions of Americans are diagnosed and/or treated using nuclear medicine and molecular imaging. The Centers for Medicare and Medicaid Services (CMS) currently sets Medicare hospital payment rates for nuclear medicine procedures and radiopharmaceutical drugs that often do not cover the provider costs of all diagnostic radiopharmaceuticals. This lack of coverage threatens patient access to care and Congress needs to make sure that CMS appropriately pays for all diagnostic radiopharmaceuticals.

SNMMI’s 2015 Capitol Hill Day was a great success! Advocacy is an ongoing effort that is strengthened by the connections made between SNMMI members and their congressional representatives. We thank everyone who took time out from their busy schedules to participate.

**SNMMI Meets with FDA to Discuss Compounding**

The Society of Nuclear Medicine and Molecular Imaging, along with several other specialty societies, met with the U.S. Food and Drug Administration (FDA) on Tuesday, April 28, for a listening session on compounding. SNMMI previously met with FDA on the same topic in the fall of 2014. SNMMI reiterated its message that nuclear pharmacy is a specialty practice of pharmacy, distinct, and separate from manufacturing. Additionally, a nuclear pharmacy is also distinct from a Positron Emission Tomography (PET) drug production facility.

The FDA has yet to release guidance on radiopharmaceutical compounding. SNMMI recommended that the FDA accept specific definitions for radiopharmaceutical preparation and minor deviations submitted in November 2014. As previously communicated in the November/December 2014 HPRA Newsletter, SNMMI, in conjunction with the American Pharmacists Association, the Council on Radionuclides and Radiopharmaceuticals, the National Association of Nuclear Pharmacies and United Pharmacy Partners, Inc., submitted a consensus statement regarding the distinction between radiopharmaceutical compounding and preparation. How the FDA chooses to define these terms will determine the impact guidance has on members. SNMMI is closely monitoring this issue and will provide members with updates as they occur.

The comment letters can be found [here](#).

**SNMMI Submits Comments on Patient Release Practices for Radioiodine I-131**

On Monday, May 4, SNMMI and ACNM submitted comments on patient release practices for radioiodine (I-131). The Nuclear Regulatory Commission issued a request for information concerning patient release practices and intends to utilize the information obtained to verify assumptions made concerning patient release guidance. In the Federal Register notice, the Commission questioned the availability of consistent and clear patient friendly and timely patient release information. The NRC intends to gain input from as many stakeholders as possible.

The comments submitted to the NRC include a review of the relevance, quality, scientific rigor and applicability of various patient release practice websites. SNMMI and ACNM believe collecting information on patient release practices will help create more informed recommendations across healthcare systems.

The full comment letter can be found [here](#).

**SNMMI Releases Executive Summary from FDA Stakeholder Meeting**

SNMMI finalized its executive summary of the broad FDA Stakeholder meeting held in the fall of 2014. The meeting goal was to facilitate the approval of new radiopharmaceuticals and their great potential to sustain the field of nuclear medicine and molecular imaging, and more importantly, to translate these agents’ promise to clinical care. The meeting brought together representatives of academic medicine, industry, government agencies, and professional societies. Meeting participants discussed four topics related to the meeting goal.

- Market/commercialization barriers
- Strategies to improve the current approval process
- Possible new pathways
- Outcome measures for FDA and CMS
SNMMI’s Center for Molecular Imaging Innovation and Technology with the World Medical Imaging Society are planning a follow-up meeting to be held in November 2015.

Read the Executive Summary here.

**House Energy and Commerce Committee Release 21st Century Cures Discussion Document**

After a year of hearings, white papers, and more than two-dozen roundtables, the bipartisan Energy and Commerce Committee has released a discussion draft on the 21st Century Cures Initiative. The society has previously submitted comments on the initiative, led by Committee Chairman Fred Upton (R-MI) and Rep. Diana DeGette (D-CO). SNMMI’s comments relate to the challenges of the current regulatory and delivery system to ensure the continued advancement of medical science and clinical care in the United States. The society requested that the Committee examine the current FDA regulatory process used to approve diagnostic radiopharmaceuticals. Modifying the current pathway will help spur continued investments and innovations in the healthcare sector that may translate into treatments and cures for patients worldwide.

The discussion draft released includes several of the provisions below, among other directives:

- Incorporate the patient perspective in the discovery, development, and delivery process
- Increase funding for the National Institutes of Health, both through reauthorization and $10 billion over five years in mandatory funding, starting in FY 2016
- Foster development of treatments for patients facing serious or life-threatening diseases
- Repurpose drugs for serious or life-threatening diseases and conditions. Modernize clinical trials

Read the full discussion draft here.

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**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.

- SNMMI, ACNM and ACR submitted a joint comment letter on ending data collection for NaF-18 PET on April 8, 2015.

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**Upcoming Events/Deadlines**

- SNMMI’s 2015 Annual Meeting will be June 6-10, 2015.

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