Important Upcoming Events at SNMMI Annual Meeting in Baltimore

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The Coalition would like to make you aware of some important events at the upcoming SNMMI annual meeting in Baltimore. We hope you can attend!

On Friday, June 5 from 9 to 10 am in the room Ruth in the Baltimore Hilton Hotel, the Coalition, led by Sally Schwarz, R.Ph. and Henry VanBrooklin, Ph.D., will hold a public meeting to review activities over the last year and to discuss future directions.

The Coalition is co-sponsoring a CE session with the Radiopharmaceutical Sciences Council (RPSC) on Monday, June 8, in Room 317 of the Baltimore Convention Center. The title of this session is “Current Topics in FDA Reviews and Inspections of PET Drug Manufacturers.” The session runs from 4:45 to 6:15 pm and includes the following presentations:

- Current topics in FDA reviews and inspections from the perspective of a small entity, Steve Mattmuller, MS, RPh, BCNP
- Current topics in FDA reviews and inspections from the commercial perspective, David Wilson, BS, RPh
- Reporting changes to an approved NDA or ANDA, Michael Nazerias, M.S.
- Overview of a sterility assurance program for PET drugs, Eric Webster

An additional session has recently been added to the program. The additional session is entitled “Update on Current Topics at the USP” and takes place immediately after the previous session on Monday, June 8, in Room 317 of the Baltimore Convention Center. The goal of the new session is to provide an update on the latest activities at the USP related to PET drug monographs and the revision of general chapters for PET drugs and radioactivity. In addition, information will be provided for the next revision cycle and future directions at the USP. The session runs from 6:20 pm to 6:50 pm and includes the following presentations:

- Brief update on USP monographs for PET drugs, Steve Zigler, Ph.D.
- Progress on general chapters pertinent to nuclear medicine, Steve Zigler, Ph.D.
- Update on new revision cycle 2015-2020, Ravi Ravichandran, Ph.D.

Finally, a session entitled “FDA: Imaging Drug Development – Regulatory Issues” takes place on Tuesday, June 9, from 10:00 am to 11:30 am in Room 318-319 of the Baltimore Convention Center. This session is sponsored by the Health Policy and Regulatory Affairs group at SNMMI and includes the following presentations:

- Chemistry, manufacturing, and control (CMC) issues in applications, Ravi Kasliwal, Ph.D.
- Nonclinical requirements for low dose diagnostic agents: past, present, and envisioning the future, Adebayo Laniyonu, Ph.D.
- Efficacy considerations for imaging product approval, Louis Marzella, MD, Ph.D.
- Statistical aspects of evaluating diagnostics, Thomas Gwise, Ph.D.
- PET products: case histories and inspectional updates, Krishna Gosh, Ph.D.
- Ge-68/Ga-68 Generators – FDA perspective, John Amartey, Ph.D.