

Compounding Joint Task Force  
June 5, 2015  
Minutes

Hilton Baltimore  
Calloway A-B

**Attendees:** Scott Holbrook, Jeff Norenberg, Michele Panichi-Egberts, Stephen Dragotakes, Neil Petry, Sue Bunning, Jesse Schoolnik, Caitlin Kubler

**Guests:** Margaret Donovan, Sara Johnson

**1. Approval of the Agenda**

Cochair Holbrook opened the meeting at 7:05 am. The agenda and minutes were approved.

**2. FDA Listening Session Follow-up**

Mr. Dragotakes provided a brief background on the committee's progress to date on compounding. Since September for 2014, SNMMI has participated in two listening sessions hosted by the FDA. The most recent listening session demonstrated that the FDA is making progress on radiopharmaceutical compounding guidance. FDA has indicated that more follow up will be necessary to develop a comprehensive guidance document. FDA noted that the process is ongoing and something may be available by late summer or early fall. Specifically the FDA had concerns about our definitions for "compounding" and "preparation." The committee has prepared a follow-up letter to address these concerns, as well as other concerns regarding patient name, bulk-drug substance/shortages, and interstate delivery.

Alan Kirschenbaum provided comments on the committee letter and some committee members had concerns with the section on bulk drug substances/shortages. Dr. Norenberg provided rationale about shortages and bulk drug solutions and potential strategies the FDA could implement to avoid issues, such as selecting specific items for the "do not compound due to difficulties list." Dr. Norenberg suggested the letter be amended with the follow language,

"The Society of Nuclear Medicine and Molecular Imaging does not support compounding copies of commercially-available radiopharmaceutical kits in anticipation of future use, except during drug shortages or to meet the unique needs of an individual patient."

Ms. Kubler will update the letter with the new language and recirculate to the group for approval.

**3. Educational Content for Members**

Ms. Kubler will send out a doodle poll to schedule a follow-up call to discuss educational content for members on compounding. The call will be scheduled in the follow two weeks from the Annual Meeting.

**4. New Business**

No new business was discussed.

**5. Adjournment**

The meeting was adjourned at 8:00 am.