SNMMI COR Submits Recommendations, White Paper on Compounded Sterile Radiopharmaceuticals to USP

On September 29, SNMMI leadership sent a letter to the U.S. Pharmacopeial (USP) Convention (Rockville, MD) outlining consensus recommendations designed to strengthen USP compounding standards for sterile radiopharmaceuticals. The letter, signed by Sally Schwarz, MS, RPh, SNMMI president, represented the conclusions of the SNMMI Committee on Radiopharmaceuticals (COR) and was accompanied by a white paper on the topic. Both the letter and the white paper included background information on the evolution of standards and common practices for sterile compounding in radiopharmaceuticals, as well as the roles of the USP, FDA, and the COR; current challenges; and 3 recommendations from the COR to strengthen USP compounding standards. Included in the white paper was a timeline of key events in USP standards and FDA regulations for radiopharmaceuticals and nuclear pharmacy (Fig. 1).

The COR praised the USP's more than 60-year history of effectively developing public standards and defining and refining these through individual drug monographs and chapters. The authors of the white paper noted that through these publications, "the USP has consistently exceeded their mandate to improve global health through public standards, even during times when substantial changes in regulations and the marketplace have created formidable obstacles for radiopharmaceuticals." However, the authors also pointed to a lack of overall definition of common practices in nuclear pharmacy that constitute compounding: "Given the pivotal role the USP has played in other public standards for radiopharmaceuticals and the predominant role played by pharmacy in the field of nuclear medicine, it is surprising that a comprehensive delineation of compounding practices for sterile radiopharmaceuticals does not exist in the USP." The group noted that the current USP standard (<797>) is broad and contains standards for compounding across the entire spectrum of sterile preparations, with much information that does not apply to radiopharmaceuticals. "From a practical standpoint," the authors stated, "this has created a public standard that is difficult to understand, both on the part of pharmacy practitioners and state Boards of Pharmacy.... In its current form, <797> does not provide a clear and effective public standard for compounding practices in nuclear pharmacy."

The 3 recommendations from the COR, also endorsed by the SNMMI Board of Directors, were intended to "strengthen USP standards associated with all aspects of radiopharmaceuticals, including the compounding of sterile radiopharmaceuticals." They are reproduced here from the white paper, which, along with the SNMMI leadership letter, is available at http://ow.ly/DaqM306Gag1.

Recommendation 1: Delineate common practices that are defined as sterile compounding within the practice of nuclear pharmacy. The current lack of a universally accepted public standard that clearly and effectively delineates common practices within the practice of nuclear pharmacy must be addressed as soon as possible. The COR recommends that the USP immediately establish a panel with expertise in sterile compounding practices for radiopharmaceuticals. This panel may have to simultaneously report to the USP's existing expert committees on sterile compounding and on radiopharmaceutical monographs and general chapters. The COR recommends that the panel first conduct a survey of existing standards and information on compounding practices associated with sterile radiopharmaceuticals. Next, the panel should delineate common nuclear pharmacy practices, including those that are and

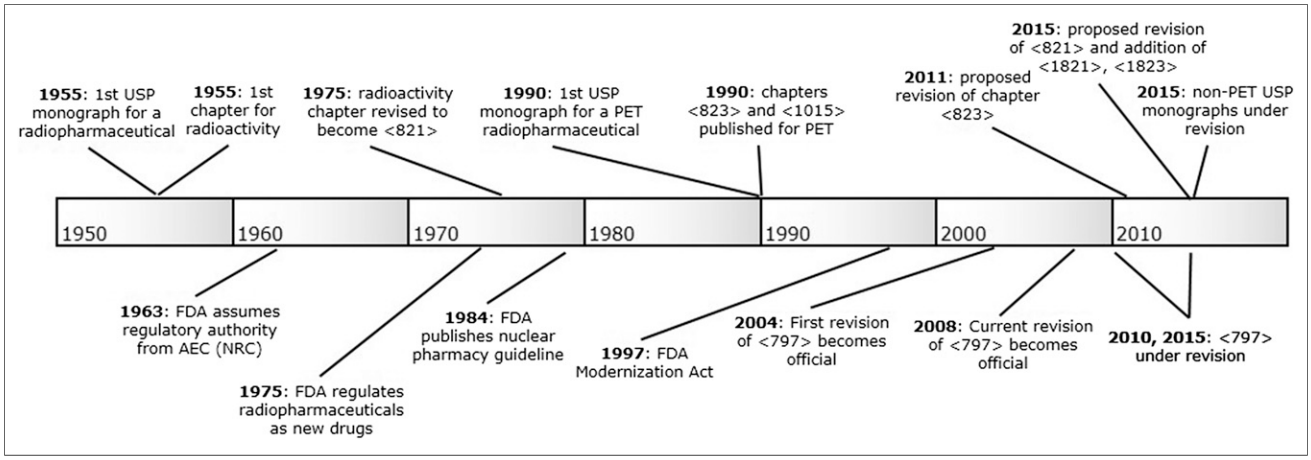

FIGURE 1. Timeline of key events in USP standards and FDA regulations for radiopharmaceuticals and nuclear pharmacy.

those that are not considered compounding. The delineated list should include but not be limited to the practices described previously in this article. The resulting list should be evaluated and revised as necessary by both existing expert committees. Finally, the COR recommends that the panel publish the resulting list as a stimuli article in the *Pharmacopeial Forum* or other appropriate publications.

Recommendation 2: Create a public standard for the preparation, compounding, and dispensing of sterile radiopharmaceuticals with the practice of nuclear pharmacy. After completing the first recommendation, the COR recommends that the panel draft a new general chapter entitled "Radiopharmaceutical Preparation, Compounding and Dispensing—Sterile Preparations" and submit it for approval by both of the above-mentioned expert committees. The COR recommends that the USP publicize the draft of a new general chapter in the *Pharmacopeial Forum* and through other standard forms of communication by the USP.

Recommendation 3: Reinstate an expert committee dedicated to all standards for radiopharmaceuticals. The USP has successfully managed many changes in public standards for radiopharmaceuticals since the transition away from a dedicated expert committee for radiopharmaceuticals in 2010. The USP has accomplished this through numerous innovative approaches that have greatly improved public standards for today's generation of radiopharmaceuticals. The COR recognizes and commends the USP for these efforts. In the spirit of continuous improvement, the COR recommends that the USP reinstate an expert committee that is dedicated to all standards for radiopharmaceuticals, including those recommended in this article and those already in existence. Membership on the committee should include experts in all aspects of radiopharmaceuticals, including manufacturing, sterile and nonsterile compounding, SPECT diagnostics, PET diagnostics, and therapeutics. The COR believes that radioactivity is the defining characteristic driving the unique nature of nuclear medicine and therefore should also define the responsibilities of this expert committee. Consequently, the COR believes the expert committee should not include responsibilities for nonradioactive products used as imaging agents (e.g., contrast agents, etc.). The COR further believes that the consolidation of all expertise under the umbrella of a single expert committee will simultaneously strengthen USP standards and create efficiencies for the USP. This is important as new diagnostic radiopharmaceuticals are developed, approved, manufactured, and compounded in the unique environment of nuclear medicine. It is especially important as new therapeutic radiopharmaceuticals, theranostics, and other technologies advance the field of nuclear medicine toward personalized health care. The reinstatement of this committee will enable the USP to play a catalytic role in these developments and to continue its innovative leadership in public standards for radiopharmaceuticals that meet the needs of patients in the U.S. and around the world.