



UNITED PHARMACY
PARTNERS

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May 14, 2019

Re: Request delay in “Draft Approaches for Addressing Training and Experience Requirements for Radiopharmaceuticals requiring a Written Directive - request for comment and notice of public meetings.”

Docket ID NRC-2018-0230

Ms. Lopas,

Thank you very much for conducting the webinar today.

While UPPI would like to see this process concluded as quickly as possible to ensure expanded access to patients, we join in asking the NRC for a 30-day delay.

A 30-day comment period for such an extensive list of questions makes it difficult to provide the necessary detailed response that the NRC staff should rely upon to undertake an assessment of an important issue like this.

Further, as discussed on the webinar, we believe that there is additional information that the NRC and other parties are collecting on the distribution of AUs which could help inform the comments of the public and the consideration of the NRC, and the NRC should consider a delay to obtain and give the public a chance to review that data.

For example, one of the challenges that the ACMUI encountered in their evaluation is a lack of objective data about the number and distribution of AUs. For instance, Dr. Palestro based part of his objection to the ACMUI moving forward was that there was additional data that had not yet been available, and Subcommittee Chair Metter stated that *“It would be my desire to have that available... But at this point in time, the data is not available... [Y]our data is something we need to look at.”*¹

As we discussed on today’s webinar, UPPI believes that the data that the NRC is assembling regarding the distribution of AUs, as well as data that is being assembled by ASTRO² to quantify the geographic distribution to ascertain whether there is a geographic shortage is important information.

Thank you for your consideration of this request, and we look forward to working with you.

Sincerely,

A handwritten signature in black ink that reads "John Witkowski". The signature is written in a cursive, flowing style.

John Witkowski
President, UPPI

¹ Transcript of Feb. 26th ACMUI meeting, P. 52-53, Emphasis added

² Dr. Ennis, a member of the ACMUI, stated that “ASTRO is actually putting together a heat map of distribution [of AUs] across the country.” Transcript of Feb. 26th ACMUI meeting, P. 55