November 14, 2018

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Chair of the Compounding Expert Committee
United States Pharmacopeia
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Submitted electronically to: http://www.usp.org/compounding/general-chapter-797

Re: Proposed USP General Chapter <797>

Dear Dr. Davidson and Compounding Expert Committee Members:

The Allergy/Immunology specialty is thankful for the opportunity to provide comments on a revised draft of Chapter 797. We start by expressing appreciation for the consideration given by the USP Expert Compounding Committee to the importance of maintaining access to allergen immunotherapy, an evidence-based, sometimes lifesaving treatment, which is dependent upon the continued ability of Allergist/Immunologists to be able to compound individual treatment sets of allergen extracts for our patients in the office setting.

We appreciated the opportunity to participate in a roundtable discussion with various stakeholders from the Allergy/Immunology specialty with Expert Compounding Committee leadership and USP, and later the addition of Expert Physician Consultants to the Expert Compounding Committee. We are also grateful for increased engagement of the USP with the AMA and look forward to continuing ongoing participation as facilitated by the AMA, as well as directly with the USP.

Revisiting the points raised as to why it is crucial that allergen immunotherapy be compounded in the office setting, our concerns have included the following:

- Allergen immunotherapy would not be possible without a beyond use date that allows for an extended treatment schedule facilitating the gradual build-up of extract administered
- Having to change source material to mix more frequently would expose patients to a significantly higher risk of a potentially deadly systemic anaphylactic reaction
- Adjustment to the content of the extract vials is sometimes necessary during the course of treatment, so being able to do that in the office and verifying the source material is key to effective treatment and protecting patient safety. Being forced to start over with new vials would be costly and cause a delay in the treatment schedule
- The dilution of allergen extracts in the compounding process includes the addition of preservatives that reduce to almost zero the risk of any infectious event from contamination

- In more than 100 years of allergen immunotherapy there are zero documented cases of infectious adverse events attributable to compounding procedures
- The specialty promotes its own standards for allergen immunotherapy that exceed the requirements of the current Chapter 797 regarding training and monitoring of compounding staff

Addendum A lists articles and studies reflecting the effectiveness and safety of allergen immunotherapy that have previously been shared with USP in the review process.

In reviewing the proposed draft chapter, we find the limitation of the scope of the chapter to exclude administration to be appropriate and sufficient for the purposes of the compendium and its standards.

The personnel qualifications included in the draft are mostly congruent with existing standards, and the new specification that any otherwise qualified staff who have not compounded in more than 6 months be re-evaluated is valid and welcomed.

The standards provided for personnel hygiene and garbing present more stringent criteria than had been in place in the version of Chapter 797 currently in effect, but we find them to be reasonable and support the introduction of these safety measures.

Members of our professional societies had expressed a variety of significant concerns as to why the PEC that was mandated in the 2015 draft Chapter 797 would not be possible in their existing office space. The flexibility of allowing either the incorporation of a PEC into the office OR the establishment of an allergenic extracts compounding area (AECA) will allow each practice to determine for itself which is the appropriate route to compliance and improved patient safety. We will provide training to our members through our annual scientific meetings, practice management related programming, and other mechanisms on how to fully comply with either option. Further, while the standards for the AECA may involve some cost and construction in some practices, we accept that the standards proposed are meaningful and present carefully chosen criteria. Similarly, the cleaning and disinfecting requirements are both sufficient and thorough, and the specialty will work to ensure adoption of the standards provided by the Chapter's anticipated implementation date.

Like the introduction of a PEC or designation of an AECA, the introduction of gloved fingertip and thumb sampling procedures adds a new requirement to the compounding process in our practices. While the lack of any reported cases of an infectious adverse event makes these seem unnecessary, the specialty is willing to acknowledge the USP Expert Compounding Committee's extensive work to create meaningful patient safety standards, and we therefore accept this additional requirement, to reflect our shared dedication to patient safety.

Because of our ongoing commitment to patient safety, the Allergy/Immunology specialty has conducted data collection on adverse events triggered by non-compounding related issues in immunotherapy, including millions of data points over many years. Building on this tradition of commitment to patient safety, we are actively looking at ways to expand this process to include sterile compounding concerns and to increase physician participation in data collection.

Our efforts regarding documentation for the purpose of patient safety have long included physician education and resources on labeling for allergenic extract prescription sets. The addition of

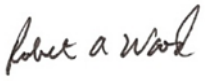
documentation of quality control procedures will be incorporated into our physician outreach and education.

Again, we appreciate the opportunity to comment on the updated draft proposed Chapter 797, and we look forward to continuing to work with the USP Expert Compounding Committee in any way we can to provide this proven and effective treatment, while maintaining both patient access and patient safety. We look forward to ongoing engagement with the USP in policy and standards development and additional issues relevant to ensuring patient safety while protecting access to care and improving patient outcomes.

We recognize and welcome the ongoing opportunity to work with the Food and Drug Administration in regard to implementation of and compliance with USP Chapter 797 standards applicable to the Allergy/Immunology specialty, as directed generally under the Federal Food, Drug and Cosmetic Act and specifically in regard to compounding under the Drug Quality and Security Act. We will also engage with states and other regulatory agencies as needed to continue to protect both patient safety and patient access to this proven effective treatment.

Thank you for your consideration of these comments as you work to finalize Chapter 797.

Sincerely,



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Safety and/or Effectiveness of Allergy Immunotherapy Citations

The American Academy of Allergy Asthma and Immunology (AAAAI). *The Allergy Report*. Milwaukee, WI. AAAAI, 2000.National Academy on an Aging Society. Chronic Conditions. A Challenge for the 21st Century, November 1999. *See* http://www.agingsociety.org/agingsociety/pdf/chronic.pdf.

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