American Academy of Allergy Asthma & Immunology

American Academy of Allergy, Asthma & Immunology Statement
Compounding Listening Session, June 3, 2016
Food and Drug Administration

Good Afternoon. My name is Dr Andrew Murphy. I am a Board Certified Allergist-immunologist practicing in Pennsylvania. I am representing the American Academy of Allergy, Asthma & Immunology, and the over 6800 physicians, research scientists, and millions of patients with allergic diseases. Thank you for the opportunity to present comments on behalf of the Academy on proposed regulations impacting allergen extract compounding in physician offices.

In February 2015, the FDA issued "Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application Guidance for Industry." Those FDA draft guidelines suggest in-office allergen extract compounding should follow the USP < 797> instructions specific to allergen extracts. The Academy submitted comments generally in support. However, we were unaware that USP was crafting a significant revision to the <797> chapter that, if approved, will directly impact allergen extract compounding and the patients allergy physicians serve.

In the fall of 2015, USP released a proposed draft revision of Chapter <797> that does not include a separate section for allergen immunotherapy extract compounding, as had been included in the previous version. The proposed changes to the USP for allergen compounding are not based on any published scientific data in which any infectious clinical problem(s) with allergen extract compounding has occurred. However, it has the potential to severely impact the health care of millions of patients suffering from allergies. The Academy and other stakeholders provided formal comments to USP earlier this year and those are attached for your review.

Allergen immunotherapy has been safely compounded and administered in allergists' offices for over 100 years. The medical literature is clear; there is no documented evidence of an infectious risk from compounding allergen extracts in the office setting. This is clearly demonstrated in a 2016 publication in the Journal of Allergy and Clinical Immunology from the Harvard Medical School providing evidence that immunotherapy using allergen extract compounding based on current guidelines does not put patients at risk for infectious complications. In this retrospective study, 3,242 patients received a total of 136,322 allergen immunotherapy injections over the 10 year study period. While 66 patients did have evidence of an infection within 5 days of receiving an allergen immunotherapy injection, none of these infections were related to the allergy immunotherapy injection. In addition, in over 40 years of practice, the United States Military's centralized allergen extract lab has not identified any infectious complication related to allergen extract compounding and administration. These data clearly support the conclusion that allergen extract preparation following current <797> guidelines do not place patients at risk for infectious complications related to allergen immunotherapy.

Anaphylaxis is the major risk in an allergen immunotherapy treatment. This risk is carefully managed under current requirements by having the extract mixed onsite by physicians and staff with a personal knowledge and experience with each and every patient. Ordering extract to be prepared elsewhere removes this important safeguard. The proposed revisions require patients to start new extract vials every month, changing source material in the extract and thus significantly increasing risk for adverse

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and potentially fatal allergic reactions. These changes therefore make a currently safe therapy become much higher in risk to the patient, forcing physicians and patients to decide if the newly increased risk is actually worthwhile, all on account of an unproven risk of infection.

Moreover, the proposed changes potentially undermine ongoing Congressional initiatives to support the use of and develop further research into the effectiveness of allergen immunotherapy. In 2011 a bi-partisan group of US Senators wrote to then-Secretary of Health And Human Services Kathleen Sebelius regarding research showing significant health and cost saving benefits of allergen immunotherapy in children and adults, encouraging " … that by further examining the clinical and economic impact of immunotherapy in both children and adults, including Medicare beneficiaries, and by developing guidelines for the diagnosis and treatment of allergic rhinitis, HHS could help increase awareness among health care providers and the general public of the potential benefits of the current treatment options." The research showing these patient benefits and healthcare utilization savings are well documented, and I am happy to provide that to you in writing in addition to this testimony. The recent proposed changes by USP undermine this bi-partisan effort, by making allergen immunotherapy, which currently is a proven, safe and effective, disease modifying therapy, into a less accessible and less effective treatment option.

Finally, the proposed changes will directly and negatively impact the ability of our active duty military to receive this therapy. Allergy immunology colleagues have indicated that the military would not be able to satisfy these requirements and in effect allergen immunotherapy would no longer be offered. Therefore active duty men and women serving away from their homes may be forced suffer severe allergic symptoms in combat surroundings and other environments that we currently are able to treat.

The FDA needs to carefully weigh proposed regulations and the impact that they have on patient care. In its proposed draft regulations, noted above, the FDA recognized the important and vital role of allergen immunotherapy in managing patients with allergic diseases. However, proposed changes in USP <797> threaten to increase the risk of anaphylactic reactions and reduce effectiveness of this proven treatment, all in an effort to prevent an adverse event that has never been reported to have happened. The proposal is overreaching and is not based on any data supporting the need for these changes. The consequences of implementing the proposed changes are profound and will directly and negatively impact access to allergen immunotherapy, imperil research into allergic diseases and most importantly, it will adversely affect the patients we serve.

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