ADVOCACY COUNCIL
of the American College of Allergy, Asthma & Immunology

Restricting the ability of physicians to prepare allergen extracts in their offices

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Issue

In November 2015, US Pharmacopeia (USP) announced proposed changes to Chapter <797> on sterile compounding that would remove the special rules for preparation of allergen extracts. The special exception rules for the preparation and administration of allergen extracts for in-office use to patients under the care of the allergist have been in place for decades and are consistent with prior Congressional Action supporting the allergen extract special rules.

Background

Allergy immunotherapy is a proven, clinically effective treatment for individuals with allergic rhinitis, allergic asthma and hypersensitivity to insect stings. The efficacy of allergy immunotherapy is well established in medical literature.

- Allergen extracts have been safely prepared by physicians using aseptic technique for over 100 years.
- The sterility record of allergen extracts prepared under current Ch. <797> rules is well-established in both the medical literature and clinical practice.
- There is no evidence that current Ch. <797> rules pose any threat to patient safety.
- The proposed rules were developed without an analysis of their impact on public health and costs to our healthcare system.
- The process did not follow USP Convention resolutions.
- The proposed rules are inconsistent with recently proposed Food and Drug Administration (FDA) Industry Guidance which recognizes special treatment for allergen extracts.

There are more than 4,200 allergists nationally who prepare and provide allergy immunotherapy extracts to their patients. It is estimated that more than 16 million allergy immunotherapy injections are administered annually in the United States. To our knowledge, there have been no reported cases of patient problems as a result of the preparation or injection of allergen extracts.

Discussion

This is a solution in search of a problem.

If the proposed rules are adopted, access to allergen immunotherapy, a proven treatment for asthma and allergic diseases, would be severely curtailed, costs of care would rise dramatically, disparities in healthcare would be increased, and overall patient health would suffer.

Allergists/Immunologists preparing and providing allergy immunotherapy extracts in their office is not new. A/I physicians have been doing this safely and effectively in their offices for over 100 years. Patients are closely monitored for reactions to the injections.

Studies reveal no complications of infection from the preparation and administration of immunotherapy performed in the physician's office. Equally important, during the 100-year history of this treatment, we are not aware of any reported cases of endotoxicity (a bacterial infection resulting in fever or toxic shock), abscesses or sepsis (severe bacterial infection in the bloodstream). This gives us assurance that allergy extracts prepared and delivered in the A/I physician's office are safe and sterile and the removal of the Ch. <797> special rules for allergen extract is unwarranted.

All allergen extracts prepared in-office are prepared using FDA-approved products. In addition, FDA has drafted guidance specifically recognizing that this type of compounding (Section 503A of the Food, Drug and Cosmetic Act) is very different from the type of compounding that resulted in tragic deaths a few years ago. It is important to note also that when Congress was crafting legislation to impose new restrictions on drug compounding, it specifically excluded allergenic extract preparation from those new requirements, concluding that the existing FDA standards were sufficient to ensure patient safety.

FDA already requires that all allergen extracts or "concentrates" be combined in sterile vials using sterile syringes - sterile compounding standards specific to allergen extracts. In addition, aseptic technique is followed and the patient-specific vials are labeled and stored in refrigerated conditions.

To the extent patient safety issues have come up with respect to allergen extracts, the adverse events are related to reactions to the antigens themselves and not the presence of contaminants in the antigen preparations. We also believe that the absence of sterility problems is due in large part to the fact that allergen extracts are diluted with phenol-containing saline or prepared from glycerinated antigens, both of which are bacteriostatic (a biological or chemical agent that stops bacteria from reproducing) at certain concentrations.

Finally, we believe the unique aspects of the doctor/patient relationship should be considered in the development of any new standards that would adversely impact the ability of A/I physicians to prepare and administer allergy extracts and immunotherapy.

Recommendation

We request that USP maintain the current Chapter <797> rules applicable to allergen extracts pending completion of a full and fair review that includes collaboration with affected stakeholders and an analysis of the profound and serious consequences on the future use of well-established safe and effective treatment for patients with allergic diseases.