



AAFA Comments at American Academy of Allergy, Asthma, and Immunology (AAAAI)

Annual Meeting

March 7, 2016

Thank you, Dr. Lemanske, and good morning.

I speak to you as the President and CEO of the Asthma and Allergy Foundation of America—AAFA—the oldest and largest not-for-profit dedicated to improving the lives of Americans with asthma and allergic disease. I want to thank quad AI for the opportunity to speak with you, and for their efforts to raise the visibility of the proposed changes to USP 797.

AAFA is an organization that is committed to fact-based policy so let me share with you some facts.

- More than 60 million Americans suffer from asthma and allergic diseases.
- For millions of these, allergy is life-limiting. Imagine the worst cold you've ever had. Now imagine it lasts 3 months. And imagine it happens twice a year. This kind of allergic disease profoundly affects quality of life. It affects workplace productivity. And it affects attendance and learning in affected children.
- For these Americans, allergy immunotherapy is life changing—and it has changed the lives for millions of Americans for the better.
- Allergy immunotherapy is critical for millions of Americans with allergic asthma, in which it has the potential to change the trajectory of a condition that is not only life-limiting—but is life-threatening. On average, 10 Americans die every day from asthma.
- Allergy immunotherapy has been administered—safely and with great effectiveness—to millions and millions of Americans for years and years.
- Allergists have mixed and delivered compounds specific for individuals, using vials of extracts—for years and years.
- Those compounds are delivered in very small volumes, intradermally. We are not talking about high volume infusion, and we are not talking about entering a body cavity.

These are facts. And there is one more:

- The changes to 797 proposed by the USP will disrupt a process that has been working safely and effectively, in a way that poses a real threat to patients. It seems certain that those changes will make it impossible for the practicing allergist to deliver timely immunotherapy to his or her patients—so access to this therapy will almost certainly be constrained. And it seems likely that these changes will increase the cost of delivering allergy immunotherapy, creating additional threats to patient access.



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At a time when we speak genuinely of our interest in “evidence-based medicine” and “patient-centered care,” AAFA needs to stand up and say “We believe that the recommendations to change regulations related to allergy immunotherapy do not fully consider the evidence, nor are they centered on the interests of patients.”

We strongly urge that these changes be rejected.

Thank you again for the opportunity to bring the patient’s voice to this panel.