Asthma and Allergy Foundation of America

Asthma and Allergy Foundation of America (AAFA)
Comments to the Food and Drug Administration (FDA)

Stakeholder Listening Session on Compounding
June 6, 2016

Good morning and thank you for the opportunity to share my perspective on the critical issue of compounding, on behalf of the more than 60 million Americans with asthma and allergic disease. My name is Cary Sennett, and I am President and CEO of the Asthma and Allergy Foundation of America (AAFA). AAFA—a not-for-profit organization founded in 1953—is the leading patient organization for people with asthma and allergies, and the oldest asthma and allergy patient group in the world (www.aafa.org). AAFA is dedicated to improving the quality of life for people with asthma and allergic diseases through education, advocacy and research.

AAFA notes that the FDA has issued guidance documents related to compounding, for public comment. AAFA looks forward to sharing our comments on those documents through the public comment process, so I do not plan to speak specifically to those today. Rather, I want to speak more generally to the issue of compounding, and express my concerns about proposed changes to standards for compounding. We believe that such changes will have a material adverse impact on patients with allergy and allergic asthma. What I have to say this morning isn't new: I will echo comments that AAFA has made previously, in written communication to the U.S. Pharmacopeial Convention (USP), and orally at a meeting of the American Academy of Allergy, Asthma, and Immunology (AAAAI).

Let me preface those comments by noting that AAFA is—like the FDA—an organization that is committed to fact-based policy. So I would like to share with you some facts.

- More than 60 million Americans suffer from asthma and allergic diseases[1].
- 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 school 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[2].

- Allergists have mixed and delivered compounds specific for individuals, using vials of extracts—for years and years.
- Allergists have administered the compounds they have mixed—safely and with great effectiveness—to millions and millions of Americans for years and years. There is not only no evidence of a risk to safety, but evidence is now coming forward that explicitly establishes the safety of allergy immunotherapy: see the recent report by Dr. Aiden Long and his colleagues in the Journal of Allergy and Clinical Immunology[3], in which no—NO—cases of infectious complications related to allergy shots could be documented, among patients at Partners receiving a total of 136,322 injections over 10 years.
- FACT: Those compounds are delivered in very small volumes, subcutaneously. 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:

- Changes to the standards for compounding allergenic extracts 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.

Our constituents tell us that their lives depend on timely access to and ongoing availability of allergen immunotherapy. AAFA is greatly concerned about the effect that proposed changes will have on patient access to immunotherapy.

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 proposed changes be rejected.

Thank you again for the opportunity to bring the patient's voice to this session. AAFA is eager to assist in any way that we can, to help further inform the FDA's deliberations. If

you require addition information or clarification, please do not hesitate to contact me at csennett@aafa.org or Meryl Bloomrosen, AAFA's Senior Vice President, Policy, Advocacy, and Research at mbloomrosen@aafa.org.

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[1] http://www.aafa.org/page/allergy-facts.aspx
[2] http://www.aafa.org/page/asthma-facts.aspx
[3] Allergen immunotherapy: No evidence of infectious risk
Diana S. Balekian, MD, MPH, Aleena Banerji, MD, Kimberly G. Blumenthal, MD, Carlos A. Camargo Jr., MD, DrPH, Aidan A. Long, MD http://www.jacionline.org/article/S0091-6749%2816%2930081-1/abstract

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