Asthma and Allergy Foundation of America

October 3, 2016

Division of Dockets Management (HFA-305)
Food and Drug Administration,
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Draft Guidance Food and Drug Administration (FDA) Notice: Insanitary Conditions at Compounding Facilities; Draft Guidance for Industry
Docket No. FDA-2016-D-2268
Submitted via: http://www.regulations.gov

To Whom It May Concern,

On behalf of the Asthma and Allergy Foundation of America (AAFA, www.aafa.org), I am pleased to submit comments in opposition to the Food and Drug Administration's (FDA) proposed guidance titled "Insanitary Conditions at Compounding Facilities: Guidance for Industry". 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. AAFA is dedicated to improving the quality of life for people with asthma and allergic diseases through education, advocacy, and research. AAFA does not support the proposed FDA Guidance because it poses a threat to patient safety and quality of care by disrupting access to and availability of allergy immunotherapy.

Our understanding is that the proposed Guidance effectively supersedes the current United States Pharmacopeia (USP) Compounding Chapter 797 requirements. AAFA has previously submitted comments and expressed concerns about potential policies and regulations that could limit patient access to allergy shots and to biologics.[1] [2] [3] [4] Allergen immunotherapy is an important treatment for allergic diseases that improves the quality of life for many allergy patients: reducing symptoms, decreasing medication costs, and diminishing the number of hospitalizations and emergency room visits.

The proposed Guidance applies to any compounding facility, and specifically includes physician offices where sterile compounds are prepared. AAFA is greatly concerned about

[1] In January 2016, AAFA submitted comments to the USP about proposed regulations that could threaten the availability of allergy shots. In March 2016, AAFA's President and CEO spoke at the AAAAI meeting about the importance of allergen shot treatments. In June 2016, AAFA's President and CEO, Dr. Cary Sennett, spoke at an FDA meeting about regulations that might impact patient access to allergy shot treatments.
[2] http://www.aafa.org/media/AAFA-Comments-USP-Panel-AAAAI.pdf
[3] http://www.aafa.org/media/AAFA-Remarks-FDA-Allergen-Compounding.pdf :
[4] http://www.aafa.org/media/AAFA-Comment-Submission-Immunotherapy-Regulations.pdf

the unintended effects that the proposed Guidance will have on patient access to immunotherapy. The Guidance would result in enormous barriers to a major component of allergy treatment. We urge the FDA to maintain the existing Guidance for immunotherapy treatment preparation in place so that allergy patients can continue to receive treatment.

While the proposed Guidance may aim to increase the safety and hygiene standards of this treatment, AAFA believes the proposed changes will have a deleterious effect and severely limit patient access to immunotherapy. We are also extremely concerned that there is no scientific data in the peer-reviewed medical literature to support the need for these more stringent requirements for allergen immunotherapy in physician offices.

The proposed Guidance will make it highly unlikely that allergists would be able to continue to mix allergen extracts for their patients in the office setting. The proposed changes 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 challenging if not 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.

AAFA believes that the proposed Guidance as related to allergy immunotherapy does not fully consider the evidence about the safety and effectiveness of immunotherapy administered in physicians' offices, nor is the Guidance centered on the interests of patients. We urge the FDA to withdraw this draft guidance until the USP 797 regulation revision process is completed.

AAFA appreciates the opportunity to offer comments to the FDA and is eager to assist in any way that we can, to help further inform the FDA's considerations. If you require additional 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.

Regards,

Cary Sennett

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