



Comments to Federation of State Medical Boards reference committee regarding draft position statement on physician in-office sterile compounding

Good morning. My name is Jennifer Namazy. I am a practicing allergist here in San Diego and I am also on faculty at Scripps Clinic in La Jolla.

I am here today on behalf of the 7,000 members of the American Academy of Allergy, Asthma and Immunology to request that the FSMB's draft position statement that physicians should not conduct in-office sterile compounding be rejected, and that the issue be comprehensively reevaluated.

In 2007 the professional societies in Allergy/Immunology worked with the United States Pharmacopeia to create appropriate procedures for sterile compounding for the administration of allergen immunotherapy, to ensure both patient access and patient safety. In late 2015, a proposed update to the USP Chapter 797 was published for public comment, and our professional societies responded that the proposed rules are a serious threat to patient access to allergen immunotherapy. We continue to work with the USP to ask that currently existing procedures for allergen immunotherapy be sustained.

The FSMB's draft position statement has the potential to adversely affect the ability of allergists across the nation to care for our patients if it results in state medical boards deciding that physicians cannot engage in sterile compounding in our offices.

Subcutaneous immunotherapy is a proven, clinically effective and safe therapy used for over 100 years to treat allergic rhinitis, allergic asthma, allergic conjunctivitis and hymenoptera allergy. It requires the use of allergen extracts commonly compounded in allergists' offices. As shown by a study in press in the Journal of Allergy and Clinical Immunology, in more than 130,000 injections given to over 3,000 patients in a 10 year

timeframe, no infectious events related to the allergy injections occurred. We have copies of the letter in press to share with you today.

I have a 15 year old patient who lives in Pine Valley. He loves to work on his father's ranch and he has won many medals in archery.

Unfortunately, he suffers a life threatening allergy to honey bees. He lives far from the local hospital, and being on allergen immunotherapy allows him to participate in these outdoor activities. However, if this position statement passes, and if USP 797 requirements for allergen immunotherapy change as proposed, we will no longer be permitted to make dilutions or changes to his extract as is sometimes required for this therapy. Therefore he will no longer have the same access to this effective immunotherapy that has already been a life-saving treatment for him. As a result, if these proposals are adopted, the results of this position statement and the proposed USP 797 guidelines *may increase his risk* of having an anaphylactic reaction.

“Above all do no harm” has been instilled in us since we first became doctors. While I understand and commend the Federation for initiating a discussion of safe compounding practices, I do not believe that all in-office compounding should be generalized as inherently and equally dangerous as the USP has proposed. Further, I do not think that the Federation best serves the interests of patients by issuing a blanket statement against any sterile compounding in physician offices. More input is needed to determine the impact on public health outcomes and healthcare resources of these decisions. Until that can be completed, on behalf of my colleagues in Allergy/Immunology, as well as on behalf of myself and my patients, and in recognition that there would be very serious repercussions for the patients of other specialty care as well, I request that this committee reject the draft position statement.

The American Academy of Allergy, Asthma & Immunology will be happy to work with you to begin that process. Thank you and I would be happy to answer any questions as the Chair may permit.