



AMERICAN ACADEMY OF
OTOLARYNGOLOGY-
HEAD AND NECK SURGERY



April 11, 2016

RE: Compounding Medications by Physicians: FSMB Draft Position Paper

Dear State Medical Boards:

The undersigned organizations are very concerned about the potential impact for patient access and patient care as a result of proposed adoption of the Federation of State Medical Boards' (FSMB) Position Paper on Compounding of Medications by Physicians. Collectively, our organizations represent more than 13,000 physicians who are board-certified or board-eligible in otolaryngology, facial plastic surgery, or allergy and immunology.

Allergists and otolaryngologists have a long history of safe in-office compounding. Specifically, there is over 100 years of history of safe compounding of allergen extracts. While we commend the FMSB for initiating a discussion of safe compounding practices by physicians, we think it is equally important to acknowledge the long safety record associated with many in-office compounding procedures and not generalize all compounding into one category of safety.

We are especially concerned about the potential impact on allergen immunotherapy administered through subcutaneous injections. Allergen immunotherapy is a proven clinically effective treatment for individuals with allergic rhinitis, allergic asthma, and hypersensitivity to insect stings. The efficacy of allergen immunotherapy is well-established in the medical literature.¹ In fact, allergen immunotherapy is the only proven therapy for allergic asthma, allergic rhinitis, allergic conjunctivitis, and hymenoptera allergy that is disease modifying and offers patients a possibility for cure.

The FSMB Position Paper sets forth a number of recommendations related to physician compounding. We are concerned that some of these recommendations could be viewed as disapproving compounding in a physician's office and eliminate the primary way in which patients access allergen immunotherapy.

The Position Paper notes that safety concerns exist if a pathogenic agent is introduced into a drug during the compounding process and that this can result in patient harm or even death. We agree that safety concerns exist whenever compounded materials are introduced into the human body as was tragically demonstrated several years ago in the case of New England Compounding Pharmacy. We also agree that compounding incorrectly has the potential to harm patients and that it should be performed according to specific protocols.

¹Cox L, Nelson H, Lockey R. *Allergen Immunotherapy: A practice parameter third update. Joint Task Force Report.* (2010) J. Allergy Clin Immunol. See <http://www.allergyparameters.org/published-practice-parameters/alphabetical-listing/immunotherapy-download/>

Otolaryngologists and allergists who prepare allergen extracts in their offices adhere to either the special protocol established by the USP in its chapter 797 on sterile compounding or to vaccine preparation guidelines developed by those who specialize in treating allergy.² To date, there have been no reported adverse events or harm to patients resulting from sterility issues associated with allergen extract preparation. It should also be emphasized that allergen immunotherapy is delivered subcutaneously; a route not noted in the previously reported cases of infectious complications due to compounding.

The current practice of aseptic technique for the preparation of subcutaneous immunotherapy vials is supported by several scientific studies. A prospective study over 8 months involved aerobic and anaerobic culture of 136 consecutive used vials at the 3-month expiration date after routine use in an allergy clinic; all vials had negative cultures.² A second prospective study compared the risk of bacterial contamination of allergy immunotherapy vials prepared in-office versus those mixed under a ventilation hood, with no infectious complications from repeated injections from 320 vials prepared in office, and 217 prepared under a ventilation hood.² A retrospective review of 26,795 immunotherapy injections prepared with aseptic technique over a 6-year period yielded not a single infectious complication.² Finally, in a large study involving >130,000 subcutaneous allergen immunotherapy injections in >3000 patients seen at Massachusetts General Hospitals and clinics over a 10-year period, no systemic or local infections were found related to the allergen immunotherapy injections (*in press*).

The Position Paper states that physicians should limit compounding activity to non-sterile preparations and physicians should familiarize themselves with USP Ch. 795 (non-sterile compounding) and Ch. 797 (sterile compounding). We would disagree with this statement. Allergen extracts, for example, are considered sterile preparations, and it is essential that patients continue to have access to this treatment. This recommendation fails to properly take into consideration the established safety record of allergen extract preparation and its important role in treating patients with asthma and other allergic diseases.

The Position Paper also states that the decision to treat a patient with a compounded medication must be triggered by a specific need in an individual patient and that medications should not be compounded in bulk. We absolutely agree that treatment should be used only for patients who meet the criteria. Many patients can be treated effectively for allergies with medical or environmental controls. However, once a physician, based on testing and a complete patient examination, concludes allergy immunotherapy is appropriate for the specific individual patient, there is generally no other way to provide treatment other than through a compounded product.

The Position Paper states that active ingredients included in a compound and necessary for treating the individual's specific medical condition should be reflected in the patient record. We agree. Each set of immunotherapy vials should be based on the specific antigens to which the individual is reactive, based on patient history and testing. It would certainly not be appropriate to treat a patient with antigens to which a patient is not reactive or which are not present in the environment.

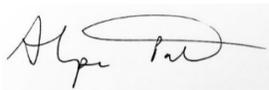
² See Lay PC, Bass R, Lin S. Allergen vial mixing and immunotherapy: Risks of infections and vial contamination. *Otolaryngology-Head and Neck Surgery* 2007; 137, 243-245 ; Lin SY, Lay PC, Hughes LF, Bass R. The safety of multidose vials in allergy immunotherapy. *Otolaryngology-Head and Neck Surgery* 2008; 139, 195-197; Gilbert KC, Sundrarahsan V, Bass RM, Lin SY. Antibacterial properties of additives used in injection immunotherapy. *International Forum of Allergy & Rhinology* 2012; 2(2): 135-138; Letz AG, Tankersley MS, Dice JP, England RW. Monitoring bacteriostasis in allergen extract mixing: 10 years of culture data. *J. Allergy Clin Immunol* 2009; 123(5): 1175-1176. Letter to the Editor ; Lay PC. Injectable immunotherapy: recommendations for safe allergen vial preparation in the office setting. *Current Opinion in Otolaryngology and Head and Neck Surgery* 2009, 17:223-225; Lay PC, Bass R, Hughes LF, Lin SY. Risks of allergy vial contamination: comparison of mixing in-office versus under ventilation hood. *Otolaryngology-Head and Neck Surgery* 2008; 139: 364-365; Rossow K, Butler MA, Lowe D, Li JT. Bacteriostatic agents and sterility requirements for allergen immunotherapy. *Annals of Allergy, Asthma and Immunology* 2011; 106:76-77

We also share the FSMB's concern that patients should not be subjected to excessive charges for compounded medications. The mixing of allergen extracts are not separately billed based on number of extracts. Rather, they are covered as part of the physician's service which includes establishing the patient's dosage and schedule and supervising the preparation. Medicare has set a fixed payment per dose that does not vary with the quantity or type of antigens included.

While we have primarily focused on in-office compounding of allergen extracts, the recommendations of the FSMB Position Paper would also have unintended consequences for many specialties, negatively impacting the care they provide. For instance, otologists often prepare compounded drops and powders in-office to treat chronic middle ear and mastoid infections. Rhinologists commonly use compounded nasal irrigations to treat chronic rhinosinusitis. Also, facial plastic and reconstructive surgeons rely on compounded topical creams and solutions for post-operative healing, as well as general skin care.

As you consider your state's position on the FSMB's Position Paper on Compounding, please consider the impact to patient access, patient outcomes, and overall healthcare costs that could result. There are many therapies that are compounded by physicians in their offices which are integral to the specialty care they provide. We would request that you not support the FSMB Position Paper as it is currently drafted and instead advocate for more physician-directed protocols to help assure safe delivery of compounded therapies.

Thank you for your consideration.



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