**TALKING POINTS FOR CALLS TO U.S. SENATORS**

I am very concerned about a proposal of the U.S. Pharmacopaeia (USP) to change the guidelines for physician office compounding in a manner that would threaten patient access to allergy shots (known as immunotherapy) if adopted by the FDA.

Senator Bob Casey is leading a bipartisan group of eight Senators (three Democrats and five Republicans) in sending a letter to HHS Secretary Burwell to express concern about this proposal. Because Senator \_\_\_\_\_\_\_ has not yet signed the letter, I am calling to provide some information and respond to any questions you may have in the hope that he/she will decide to join the other eight Senators in this effort.

There are no data to support the USP proposal. In over 100 years of effective use, there have been NO documented cases of infection resulting from immunotherapy. Nevertheless, the USP is proposing onerous new requirements for compounding of the allergen extracts that we use to treat allergy patients and reduce progression to asthma.

Immunotherapy is the only disease-modifying treatment for allergies. In addition, numerous studies have found immunotherapy to be extremely cost-effective. So it is a great concern for the millions of allergy patients that the American Medical Association has stated that the USP proposal ***“…would, for all practical purposes, eliminate this form of individual patient therapy.”***

If adopted by the FDA, USP's proposal to address a problem that does not exist will make it effectively impossible for allergy doctors to prepare these extracts in their offices. The costs to patients would increase dramatically if their allergies and asthma are poorly controlled, their immunotherapy is abruptly discontinued, and doctors are forced to use the limited number of compounding pharmacies that provide this service. As noted by the AMA, access to immunotherapy could be all but eliminated.

The deadline for signing the letter has been extended to May 26. I hope the Senator will co-sign the letter to protect allergy patients from a proposal that will increase the cost and reduce the availability and quality of the care they need.