ROBERT P. CASEY, JR.
PENNSYLVANIA

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HEALTH, EDUCATION, LABOR, AND PENSIONS
SPECIAL COMMITTEE ON AGING
JOINT ECONOMIC

United States Senate

WASHINGTON, DC 20510

April 20, 2016

Dear Colleague:

Under current regulations, allergists are allowed to compound the allergen extracts needed to make allergy shots in their offices. Although this is a type of sterile compounding, it carries lower risks than other types of sterile compounding and has been done safely in doctor's offices for decades. Physicians prepare these extracts based on the allergies of individual patients, and have developed specific expertise in this preparation that is not shared by other pharmaceutical compounders. For these reasons, allergy extract compounding has been traditionally exempt from the guidelines for sterile compounding.

Allergy shots are a proven treatment for allergies and can reduce complications such as asthma. Further, there have been no documented cases of complications due to the compounding of allergen extracts. However, despite this longstanding record of safety, U.S. Pharmacopeia (USP) has recently proposed changes to the Food and Drug Administration's guidelines for this form of compounding. USP's proposed changes would remove the exemption for allergen extract compounding, which could make it impractical for allergists to compound allergen extracts in their offices. These physicians are highly concerned that the changes could increase costs for patients and decrease access, especially since there appear to be few outside pharmacies proficient in this type of compounding.

In light of these concerns, I invite you to join a letter to Secretary Burwell at the Department of Health and Human Services (HHS). This letter relays concerns to Secretary Burwell that the data may not exist to support the proposed changes. It also asks HHS to explain how physicians will obtain the extracts they need, the impact these changes will have on coverage for allergy shots and the impact these changes could have on National Institutes of Health-funded research into allergen immunotherapy.

I hope you will consider signing on to my letter. Please contact Doug Hartman at Doug_Hartman@casey.senate.gov if you wish to join, or if you have any questions.

Sincerely,

Bob Casey, Jr.

Robert P. Casey, Jr.
United States Senator

April XX, 2016

The Honorable Sylvia Mathews Burwell
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Burwell:

We write to express our concerns about a recent proposal by U.S. Pharmacopeia (USP) to modify the guidelines that the Food and Drug Administration (FDA) has adopted for pharmaceutical compounding with respect to allergen extract compounding.

Allergen extract compounding is conducted by physicians as part of allergen immunotherapy (commonly referred to as "allergy shots"). Physicians prepare allergen extracts based on individual patients' allergies, and allergists have developed specific expertise in how to prepare these allergen extracts for their patients that is not shared by other pharmaceutical compounders.

In 2015, FDA proposed guidelines for allergen extract compounding separate from the General Chapter 797 guidelines for sterile pharmaceutical compounding. More recently, USP has proposed removing this exemption for allergen extract compounding. This proposal has been made in the absence of any sentinel event or evidence presented by USP that infectious complications have occurred under the current policy. Physician and patient organizations have expressed great concern that this proposed change could make allergen extract compounding so complicated and expensive that it would virtually eliminate patient access to allergen immunotherapy.

A 2013 report by the Agency for Healthcare Research and Quality concluded that allergen immunotherapy (AIT) is both safe and effective.[1] Physicians have treated millions of patients with AIT for over a century, with no reported cases in the medical literature of patients developing an infection as the result of a non-sterile allergen extract. Thus, we respectfully request that you conduct an assessment to determine whether there is an evidence-based rationale for the proposed change.

We emphasize our strong support for the efforts of the FDA and USP to ensure the safety of pharmaceutical compounding, but question whether the data exist to support these changes to the standards for allergen extract compounding, as currently performed in physician offices.
In addition, we request your response to the following questions:

- It is our understanding that the USP proposal will make it impractical for allergists to compound immunotherapy prescriptions in their offices. In this case, how will physicians procure allergen extracts for individual patients? Are there a sufficient number of

[1] http://www.ncbi.nlm.nih.gov/books/NBK133240/

compounding pharmacies in the country that offer this service? Would this increase the cost of allergen extract preparation?

- Currently, Medicare and Medicaid cover the cost of in-office allergen extract compounding. It is our understanding that there is no billing code under which a physician can charge for extracts prepared by a third-party vendor. In this case, we presume that the cost of this service – currently covered by most medical insurance programs –would be passed on to the patient. How would physicians seek appropriate reimbursement for extracts prepared by a third-party vendor without an appropriate billing code? What would the impact of this change have on insurance coverage of allergen immunotherapy and patients' ability to access such treatment?

- There are several ongoing NIH-funded clinical trials involving allergen immunotherapy. Would the USP proposal have an adverse impact on this research?

Allergen immunotherapy has long been known to prevent the development of new allergies and asthma; it also reduces overall health care costs. It is essential that this proposed change be carefully examined for its potential impact on patients, which could significantly reduce access to allergen immunotherapy and increase costs, without any evidence that it would prevent infections that, to date, have not been documented in any patients.

Thank you for your attention to this important issue. If you have any questions, please contact Sara Mabry in Senator Casey's office at sara_mabry@casey.senate.gov. We appreciate your timely response to this letter.

Sincerely,

Robert P. Casey, Jr.
United States Senator