

March 16, 2018

The Honorable Alex Azar Department of Health and Human Services 200 Independence Avenue, SW Washington, DC 20201

Dear Secretary Azar,

As you know, antimicrobial resistance is one of the greatest threats facing our health system and our nation. The Centers for Disease Control and Prevention (CDC), estimates that more than two million people are infected with antibiotic-resistant organisms, resulting in approximately 23,000 deaths annually.

Congress has been actively engaged in the development of policies to address this rapidly growing concern. To date, this has focused largely on the support of efforts to develop new antibiotics and more wisely use those that we already have including the use of antimicrobials in food-producing animals. We write today to bring attention to another antimicrobial resistance concern: overuse of broad-spectrum antibiotics due to widespread avoidance of penicillins for patients with unverified self-reported penicillin allergy.

Unverified patient-reported penicillin allergies affect the choice of antibiotics that providers can use to treat infections in these patients. About 10 percent of the population reports a history of penicillin allergy, but studies have shown that when such patients undergo formal evaluation via skin testing performed by a board-certified allergist/immunologist, approximately 90 percent or more of those reporting an allergy are not allergic to penicillin, and are therefore able to take penicillin-related antibiotics safely.

According to published research, an unverified history of penicillin allergy can contribute to increased rates of serious and potentially life-threatening antibiotic resistant infections, as well as longer hospitalizations, higher costs, and greater risk for adverse effects of alternative antibiotics. The American Academy of Allergy, Asthma and Immunology recommends testing by a board-certified allergist/immunologist to confirm a penicillin allergy for individuals who believe they have a penicillin allergy or who have documentation in their health record of such allergy. Those who are found to not have a true allergy would be able to use narrow-spectrum penicillin-related antibiotics to treat many infections instead of less targeted antibiotics that pose greater risk for adverse effects. Using narrow-spectrum antibiotics can result in lower health care costs and decreased antibiotic resistance.

Penicillin allergy testing, and penicillin desensitization are important parts of comprehensive antibiotic stewardship. The testing is safe, easy, and effective, and can be performed even in critically ill patients and pregnant women. Additionally, people with a verified penicillin allergy who have an infection for which there is no equally effective alternative can be offered penicillin desensitization, which gradually increases the dose of penicillin to the patient in order to stop the allergic response. This procedure entails administration of graduatly increasing doses of penicillin in a fashion that effectively shuts off the allergic response and permits an allergic individual to receive penicillin safely. Penicillin desensitization can be a life-saving intervention.

The Department of Health and Human Services can play an important role in promoting penicillin allergy testing and desensitization. We would appreciate your response to the following questions:

- 1) How are HHS agencies engaged in the development of guidelines or protocols to increase penicillin allergy testing and desensitization?
- 2) What steps have been taken by the National Institutes of Health or other HHS agencies to implement the recommendations of the report of an NIH workshop on drug allergy published in 2015?
- 3) What have HHS agencies done to support the development of hospital and community-based programs to educate patients and providers about the low incidence of penicillin allergy and the need for testing?
- 4) What steps has HHS taken to encourage providers to correctly identify penicillin allergies including development and adoption of quality measures and other federal health and safety standards?

We look forward to receiving your responses to the above questions and to working together in the future to combat antimicrobial resistance.

Sincerely,

Benjamin L. Cardin

United States Senator

Orrin G. Hatch

United States Senator

Michael F. Bennet

United States Senator