

Testimony of Louis Mendelson, M.D.

for the

Public and Outside Witness Hearing

before the

Subcommittee on Labor, Health and Human
Services, Education, and Related Agencies

Committee on Appropriations
U.S. House of Representatives

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Chairman Cole, Vice-Chairman Womack and Ranking Member DeLauro- thank you for the opportunity to testify today and for your recognition that antibiotic resistance requires strategic action and investments from Congress and federal agencies.

My name is Louis Mendelson. I have worked as an allergist in private practice in Connecticut for over 40 years, have been a professor at the University of Connecticut School of Medicine for 35 years, and have directed an allergy clinic at Connecticut Children's Medical Center for nearly 20 years. I have served as the President of the Connecticut Allergy Society and the New England Society of Allergy and on the Board of Directors of the American Academy of Allergy, Asthma & Immunology (AAAI) and received leadership and distinguished clinician awards from AAAI. I have spent my professional life working with patients and families facing severe allergies.

I am here today to talk to you about antibiotic resistance (AR) and urge the Labor, Health, Human Services (LHHS) and Education Appropriations Subcommittee and Congress to encourage the National Institutes of Health (NIH) to fund research and development for products to accurately diagnose patients with penicillin allergies. I also urge you to direct the Centers for Disease Control and Prevention (CDC) and other federal health agencies to promote awareness about penicillin allergy and skin testing to the public and medical professionals and to develop and disseminate best practice guidelines for penicillin testing and appropriate antibiotic use. Penicillin allergy testing is an existing and economical means to combat AR and significantly improve patient outcomes.

Antibiotic resistance is one of the most serious public health threats facing the world today. The CDC estimates that AR is responsible for 2 million illnesses and 23,000 deaths in the United States each year. Further, at least 240,000 Americans develop *C. difficile* infections each year as a consequence of antibiotic misuse. AR limits the ability to quickly and reliably treat bacterial infections, and the rise of resistance could hamper the ability to treat even common infections, such as strep throat and ear infections. Performing complicated medical procedures like surgery and dialysis could become life-threatening due to AR.

In terms of costs, the CDC reports that AR infections account for at least \$20 billion in excess direct health care costs and up to an additional \$35 billion in lost productivity due to hospitalizations and sick days each year. In this period of budget caps, sequestration, and efforts to contain health care costs, especially in Medicare and Medicaid, the potential cost savings of successfully addressing AR are enormous.

Antibiotic misuse--the unnecessary use of an antibiotic, or the use of a more powerful antibiotic than necessary--has enabled the rise of AR. An enormous contributor to this problem is the mislabeling of patients as allergic to penicillin. Thirty million people or--10% of the United States population--are medically categorized as allergic to penicillin, based on prior reactions, confusion of routine medication side effects for allergy symptoms, or inaccurate memory. When tested for penicillin allergy, however, about 90%% of those 30 million people test negative and can safely take penicillin without the risk of an acute allergic

reaction. Penicillin is a very effective drug to treat infections, and it is far more cost-effective and generally safer with fewer side effects than expensive broad-spectrum antibiotics.

In a recent publication by Macy et al. (Journal of Allergy and Clinical Immunology, 2014), the clinical experience of over 50,000 hospitalized patients with a history of penicillin allergy was studied. Patients categorized as penicillin allergic were more likely to receive broad-spectrum antibiotics and up to 30% more cases of antibiotic-resistant infections developed in those patients. Further, the average hospital stay was 0.6 days longer with an aggregate cost of \$65 million for patients categorized as penicillin allergic. If penicillin allergy skin tests had been used, these effects could have been mitigated in more than 90% of these patients, and more than 90% of the extra health system costs avoided.

Basic knowledge of penicillin skin testing to rule out penicillin allergy has been available since the early 1970's, but skin testing has unfortunately been significantly under-utilized. There is a lack of awareness among physicians, public health officials, and policy makers about the critical value of penicillin skin testing. Neither the previous Congress's version of Chairman Upton's and Representative DeGette's 21st Century Cures bill nor the President's initiative on antibiotic resistance mentions penicillin allergy and testing. The major purpose of my testimony today is to bring this important issue to the Congress's attention so that this omission can be remedied.

Since the 1970's, multiple studies have shown that five skin-testing reagents are needed to fully evaluate patients suspected to be penicillin allergic.

One of these reagents is commercially available in the United States, and efforts are underway to make the remaining four reagents commercially available.

When all of these reagents are approved by the Food and Drug Administration (FDA) and commercially available, testing can be accomplished more efficiently and more accurately, resulting in fewer mis-labeled penicillin allergies, reduced risk of AR, less costly patient care, and improved patient outcomes, as noted in the March 2015 Journal of Allergy and Clinical Immunology. Along with my testimony, I am also submitting a letter from AAAI to the FDA with this exact message. I appreciate that this committee does not fund the FDA, but the activities of the NIH, FDA, and CDC are all inter-linked, and coordination is essential to combat AR.

In 2005, two fellow allergists joined me and a pharmacologist to form AllerQuest LLC, because no pharmaceutical company was interested in bringing penicillin reagents to market for widespread clinical use. We have all been involved with penicillin allergy research since the 1970's. In 2009 AllerQuest brought back to market one of the penicillin testing reagents and has been working for the past three years with the FDA to bring the additional testing reagents to market to allow for a much more comprehensive penicillin allergy test. With the complete panel of penicillin skin-testing reagents, the test's accuracy rises from about 70-90% to about 98%. We are a very small company, though, and these efforts need to be executed on a far larger scale to reach the universe of 30 million patients categorized as penicillin allergic and to ensure that antibiotic resistance can be controlled and contained.

In summary, improved penicillin allergy diagnostics will make a significant impact on the incidence of antibiotic resistance in the approximately 27 million patients incorrectly categorized as penicillin allergic in the United States and enable the broader use of a safe, effective antibiotic, penicillin. Again, I urge Labor HHS and Congress to invest in effective and efficient ways to approach this serious problem with a focus on funding research and development for antibiotic allergy diagnostics in order to accurately diagnose patients with penicillin allergy. I also urge you to direct the Centers for Disease Control and Prevention and other federal health agencies to promote antibiotic stewardship, including sharing guidelines for appropriate antibiotic use and promoting public awareness about penicillin allergy and testing. Your leadership can enable researchers and companies to investigate and bring to market essential penicillin allergy diagnostics as part of any plan to control antibiotic resistance.

Thank you.



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The American Academy of Allergy, Asthma & Immunology (AAAAI) is a professional organization with more than 6,800 members in the United States, Canada and 72 other countries. This membership includes allergist / immunologists, other medical specialists, allied health and related healthcare professionals—all with a special interest in the research and treatment of allergic and immunologic diseases.

We have followed with great interest the issues surrounding antibiotic resistance and the resultant problems in choosing appropriate antibiotics for patients. Our members are trained to correctly diagnose and manage drug allergies, including those to antibiotics. Many patients are inappropriately diagnosed with antibiotic allergy. This often leads to the administration of alternative antibiotics that are typically more expensive, and with increased use, the propensity for the development of resistance to their antimicrobial effects.

In addition to supporting the development of new antibiotics, we urge Congress and the administration to support the development of reagents that can be used to accurately diagnose patients with antibiotic allergies. We have attached a paper published in the Journal of Allergy and Clinical Immunology citing an example of the need for FDA approval of penicillin skin testing reagents. We believe that this will result in less patients being misdiagnosed with penicillin allergy and allow the administration of older, effective antibiotics, thus decreasing the use of newer more expensive antibiotics for select patients. This will ultimately result in lower development of antibiotic resistance and better patient outcomes.

The attached paper is but one example of how we as a specialty hope to combat the problem of antibiotic resistance. We ask for your support to gain more rapid approval of better diagnostic tools to evaluate patients with histories of antibiotic allergies. We also urge increased research funding for the study of antibiotic and drug allergies in general so that we can provide our patients optimal care.

Sincerely yours,

Robert F. Lemanske, Jr.,
MD, FAAAAI
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