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April 15, 2020

Janet Woodcock, M.D.  
Director, Center for Drug Evaluation and Research  
Food and Drug Administration  
10001 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Director Woodcock;

I am writing to continue the conversation that you and your team, including Dr. Stacy Chin, Dr. Courtney McGuire, Dr. Sally Seymour, and LaShawn Sykes, had with Dr. David Lang, Dr. Tom Fleisher, and Sheila Heitzig on behalf of the AAAAI, on February 20.

As mentioned during our meeting, Dr. David Khan presented at the Feb. 27<sup>th</sup> meeting of the Presidential Advisory Council on Combatting Antibiotic Resistant Bacteria (PACCARB). We are pleased to report that his comments were very well received and generated significant discussion about the potential for more widely spread adoption of penicillin allergy testing as a means of antibiotic stewardship.

Just as in our meeting with you, there were important questions and clarifications about the positive predictive value of penicillin allergy testing, and regarding the need for careful and effective training and coordination as an important part of the process of rolling out broader use of this testing.

In the weeks since our meeting, so much has happened that was not expected. While concerns around antibiotic resistance are not in the forefront, they certainly demand attention. We believe that increasing availability of penicillin allergy testing, which would benefit significantly from expanded access to products designed for this purpose, is important to consider for the following reasons related to COVID-19:

1. Optimism about industry development of new antibiotics has seen dramatic challenges over the past year as a number of companies have halted research and testing opportunities in this area. With the pipeline for new drugs faltering, the importance of maximizing use of existing therapies becomes more important than ever.
2. Patients hospitalized and vulnerable with COVID-19 face an alarming risk from antibiotic resistant micro-organisms. As always, it is important to protect the currently available products most effective against these threats by removing the penicillin allergy label from as many patients as possible. Opportunities to expand this potential prior to any subsequent surges in hospitalizations should be identified and implemented, particularly in conjunction with any efforts to increase surveillance of resistant and deadly microorganisms.

3. Considerable concern about the potential for secondary respiratory infections in patients recuperating from COVID-19 indicates a possible increased need for antibiotics. This, combined with the previous factors, increases the urgency behind the opportunity to expand penicillin allergy testing.

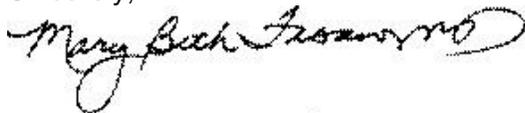
Last week, as a member of the Stakeholder Forum for Antimicrobial Resistance (S-FAR), the AAAAI joined letters to the Directors of both the Centers for Disease Control and Prevention (CDC) and the Biomedical Advanced Research and Development Authority (BARDA) requesting that a portion of the emergency supplemental funding be used to expand stewardship and data collection on antibiotic use as well as surveillance of secondary bacterial infections and resistance related to COVID-19, and to provide support for antibiotics companies through the purchase of innovative antimicrobials to the Strategic National Stockpile, respectively.

Similarly, the AAAAI respectfully suggests that the FDA pursue any opportunities to bolster efforts to expand confirmation testing of patient-reported penicillin allergy testing as may be possible as part of supplemental funding allocated to the FDA.

Following the cancellation of the AAAAI's annual meeting, our volunteer leaders are working diligently to develop online educational resources to provide to our members. In addition, the AAAAI has launched a COVID-19 Response Task Force that continually provides updates for our members, other healthcare providers, and the public to help make patient care accessible, both related to the pandemic and in response to the ongoing needs of our allergy, asthma and immunology patients. One resource currently in development will help our members facilitate drug allergy testing by other clinicians via telemedicine, including penicillin allergy testing. We are continuing to explore additional opportunities to build this practice within our specialty and elsewhere for the important public health reasons we discussed in February and addressed in this letter.

Thank you again for taking the time to meet with us to discuss the importance of penicillin allergy testing. The AAAAI looks forward to additional discussion and to providing any further information or assistance that might be helpful. Please contact Sheila Heitzig, JD, MNM, CAE, AAAAI Director of Practice and Policy, at (414) 272-6071 or sheitzig@aaaai.org if you have any questions.

Sincerely,



Mary Beth Fasano, MD, MSPH, FAAAAI  
President, AAAAI

cc:

Mary Thanh Hai, Director, Office of Drug Evaluation (ODE) III, FDA

Stacy Chin, Medical Officer, Division of Pulmonary, Allergy, and Rheumatology Products (DPARP), FDA

Courtney McGuire, Medical Officer, Division of Pulmonary, Allergy, and Rheumatology Products (DPARP), FDA

Sally Seymour, Director, Division of Pulmonary, Allergy, and Rheumatology Products (DPARP), FDA

Dr. David Lang, MD, FAAAAI, Immediate Past-President, AAAAI

Dr. Thomas Fleisher, MD, FAAAAI, AAAAI Executive Vice President