October 26, 2016

The Honorable Lamar Alexander
Chairman, Committee on
Health, Education, Labor & Pensions
U.S. Senate
Washington, D.C. 20510

The Honorable Patty Murray
Ranking Member, Committee on
Health, Education, Labor & Pensions
U.S. Senate
Washington, D.C. 20510

Dear Senators Alexander and Murray,

The Pew Charitable Trusts, Infectious Diseases Society of America, BD (Becton, Dickinson and Company), and the American Society for Microbiology thank you for your continued commitment to addressing antibiotic resistance. We appreciate the strong, bipartisan leadership the HELP committee has shown in tackling this growing public health threat, including championing the Generating Antibiotic Incentives Now (GAIN) Act in 2012 and passing the Promise for Antibiotics and Therapeutics for Health (PATH) Act out of Committee in 2016. These two bills address critical challenges to new antibiotic development, a key component to any strategy to combat antibiotic resistance.

However, we need to ensure that all antibiotics - both new and existing - are used appropriately in order to conserve their effectiveness. To do that, we urge you to consider including language in the Senate health innovation package that will ensure the availability of timely and accurate breakpoint data that will help healthcare workers determine which antibiotics will be most effective to successfully treat their patients' bacterial infections. As antibiotic resistance develops and bacteria evolve, breakpoints change and need to be updated.

Under current law, FDA is required to regularly update antibiotic labels with new breakpoint information. However, the process is extremely time-consuming and resource-intensive for the FDA and these delays can cause real harm.

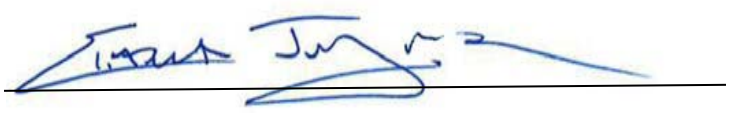
In fact, a recently published study showed that a typical delay in the use of updated breakpoints for carbapenem-resistant *Enterobacteriaceae* (CRE) could result in the accrual of an additional 1,821 CRE carriers in just one county in California.[1] CRE has been identified as an urgent public health threat by the CDC. These bacteria are resistant to nearly all available antibiotics and as this study demonstrated, the threat is only compounded by the delay in providing doctors with the most current data to make informed treatment decisions.

Health care facilities often rely on antimicrobial susceptibility test (AST) devices to identify patients with dangerous, multi-drug resistant infections for whom certain infection control protocols must be activated to prevent the further spread of the resistant organism. Without updated breakpoints, an AST device may misclassify infecting bacteria, putting patients at risk of misguided and ineffective care, and putting other patients, family members, and others at risk of exposure.

Section 2121 of H.R. 6, the 21st Century Cures Act, would streamline the process of updating breakpoints. This provision is supported by a broad coalition of stakeholders, including public health organizations, infectious disease specialists, and companies who manufacture the devices that test susceptibility. FDA has testified that it also supports streamlining the process. This legislation would give providers access to timely and accurate data so they can determine which drug is right for their patients. This is important for the individual patient, who needs the right antibiotic at the right time, but also for the broader community, which will benefit as improved antibiotic selection slows the development of resistant pathogens. The legislation permits FDA flexibility in utilizing external standard-setting organizations, if deemed appropriate, to update drug labels and AST devices, and establishes a new website for the most updated breakpoint information. We strongly support the language passed in the House bill.

Streamlining the process would bring breakpoints and antimicrobial susceptibility testing into the 21st century. The Senate has an opportunity to join the House in making a meaningful difference in the fight against antibiotic-resistant bacteria. We urge you to include this provision as you work to finalize the Senate innovation legislation.

Sincerely,



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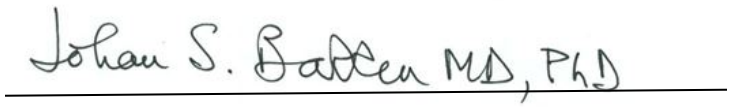
The Pew Charitable Trusts

[1]Sarah M. Bartsch, et al., "Impact of Delays between the Clinical and Laboratory Standards Institute (CLSI) and the Food and Drug Administration (FDA) Revising Interpretive Criteria for *Carbapenem-Resistant Enterobacteriaceae* (CRE)," *Journal of Clinical Microbiology* (2016): JCM-00635, doi: 10.1128/JCM.00635-16.



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