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November 18, 2016

Leslie Kux  
Associate Commissioner for Policy  
U.S. Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

***Re: Docket No. FDA–2016–D–2561: Draft Guidance for Industry on Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices; Draft Guidance for Industry and Food and Drug Administration Staff***

Dear Ms. Kux:

The Association for Professionals in Infection Control and Epidemiology (APIC) appreciates the opportunity to provide comments on *Draft Guidance for Industry on the Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices*. APIC is a nonprofit, multidisciplinary organization representing over 15,000 infection preventionists whose mission is to create a safer world through prevention of infection. Our members are charged with the prevention and control of healthcare-associated infections and take an active role in addressing the serious threat that antibiotic resistance poses to the public, our economy, and our national and global security. Coordinated effort between drug developers and test manufacturers will ensure reliable and efficient detection of developing antimicrobial resistance.

Efforts have been underway for several years to assure that not only appropriate antibiotics are used by clinicians, but also that research and development initiatives continue to assure that antimicrobials are available to treat all microbial threats.<sup>1,2</sup> This draft guidance will support those efforts.

APIC applauds the coordinated approach that the Food and Drug Administration (FDA) is proposing. Further, we appreciate that the FDA recognizes the benefits of bringing the antimicrobial susceptibility test device (AST) manufacturers and the drug developers together. Having a new antimicrobial available to treat a potentially life-threatening infection is comforting, but knowing that the new antimicrobial is working for that patient's specific resistant microorganism can mean the difference between life or death. The willingness for the Center for Devices and Radiologic Health and the Center for Drug Evaluation and Research to have a coordinated approach will benefit patients by reducing the potential for development of drug resistant microorganisms and improving patient outcomes through the timely use of appropriate antibiotics. APIC supports this draft guidance.



Sincerely,

*Susan Dolan*

Susan Dolan, RN, MS, CIC, FAPIC  
2016 APIC President

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<sup>1</sup> The White House, National Strategy for Combating Antibiotic-Resistant Bacteria. September 2014.  
Available at: [https://www.whitehouse.gov/sites/default/files/docs/carb\\_national\\_strategy.pdf](https://www.whitehouse.gov/sites/default/files/docs/carb_national_strategy.pdf) accessed  
November 11, 2016.

<sup>2</sup> The White House, National Action Plan for Combating Antibiotic-Resistant Bacteria. March 2015.  
Available at:  
[https://www.whitehouse.gov/sites/default/files/docs/national\\_action\\_plan\\_for\\_combating\\_antibiotic-resistant\\_bacteria.pdf](https://www.whitehouse.gov/sites/default/files/docs/national_action_plan_for_combating_antibiotic-resistant_bacteria.pdf) accessed November 11, 2016.