February 20, 2014

Hon. Peter Roskam
U.S. House of Representatives
227 Cannon HOB
Washington, DC 20515

Dear Congressman Roskam

We are writing to support your legislation that modifies the Medicare New Technology Add-on Payment (NTAP) program to address critical market barriers for much-needed antimicrobial products. As you know, novel antimicrobial products, especially those targeting multidrug-resistant bacteria, face significant barriers that run counter to typical pharmaceutical market dynamics, including administration predominantly in acute care settings, episodic use, and being held in reserve to control resistance. However, when patients are faced with infections that are resistant to all other available therapies, these drugs can have an enormous impact by providing a cure that saves lives as well as reducing hospital costs. Without a steady development of new products that keep pace with pathogens increasingly resistant to existing therapies, patients will face a world without effective treatments for even commonplace infections.

Antibiotics are undervalued when taking into consideration the life saving and morbidity benefits they confer. Recent regulatory reforms aimed at expediting approval of important antibiotic and antifungal drugs are helpful in encouraging challenging and costly research and development. More needs to be done, however, to improve the viability of products that address high unmet needs in the inpatient setting. In most situations, as new therapies are introduced, Medicare's bundled payments based on a patient's diagnoses and procedures can be recalibrated to reflect increased costs, but it requires both significant time and volume use of that new therapy—two factors that are absent from limited-use antimicrobial products. The NTAP program is available to increase payment for new therapies in some instances, but the payments are still inadequate and only available for a short time.

Your proposal would modify the NTAP program to more appropriately reimburse for products targeting bacterial and fungal pathogens associated with high rates of mortality or serious morbidity, and for which we have limited or no alternative treatments. This modification is an important incentive to support enhanced research efforts and could provide sufficient encouragement for manufacturers to remain in or reconsider antimicrobial product development.

Dr. Janet Woodcock, Director of the Food and Drug Administration, has said, “We are facing a huge crisis worldwide not having an antibiotics pipeline.” Dr. Tom Frieden, Director of the Centers for Disease Control and Prevention, has acknowledged, "[W]e will soon be in a post-antibiotic era.” These warnings are real, and we thank you for your leadership in proposing appropriate Medicare policy to help research-based pharmaceutical manufacturers meet the challenges of this serious and worsening situation.

Sincerely,

Antimicrobial Innovation Alliance
- *Achaogen*
- *Astellas US*
- *AstraZeneca*
- *Forest Laboratories*
- *GlaxoSmithKline*
- *Merck & Co.*
- *The Medicines Company*

California Healthcare Institute

Johnson & Johnson

Tetraphase Pharmaceuticals