



**ANTIMICROBIAL
INNOVATION
ALLIANCE**

December 10, 2013

The Honorable Phil Gingrey, M.D.
442 Cannon House Office Building
House of Representatives
Washington, DC 20515

The Honorable Gene Green
2470 Rayburn House Office Building
House of Representatives
Washington, DC 20515

Dear Representatives Gingrey and Green,

The Antimicrobial Innovation Alliance writes to support your legislative effort to establish a streamlined and efficient development pathway for antimicrobial products to meet unmet needs. The Antimicrobial Innovation Alliance is a diverse coalition of pharmaceutical innovators, spanning from early development-stage to global R&D and manufacturing companies, created to address the unique challenges facing the research, development, and approval of new antimicrobial products, as well as their market viability. Our mission is to work with policymakers and others to overcome these challenges and address the threat of antibacterial resistance, now and in the future.

Antibacterial and antifungal product development faces significant regulatory and economic barriers. Meeting conventional Food and Drug Administration evidentiary standards for product licensure can be cumbersome for drugs and biologics that combat complex infectious pathogens as large data sets are required, but only limited populations of patients are available from which to derive these data sets.

The development infrastructure you propose would provide support to the existing regulatory framework to allow innovative approaches for drug development and approval paradigms. Allowing the greater use of alternative trial endpoints and strong reliance on preclinical and clinical data in combination with human efficacy studies should bolster the capacity and speed with which new antimicrobials are developed. Your concept, if properly implemented, also should ensure that products licensed with limited data profiles are used properly in responding to unmet medical needs. In addition, your efforts to improve how susceptibility test criteria are established and maintained should aid the

infectious disease community's goal of using the optimal product for each specific patient's infection.

As you know, the pipeline for novel antimicrobial products is far too thin to curb the increasing public health threat from antibacterial resistance. Your legislation should aid in addressing this dangerous situation, and we thank you for your leadership and continued focus on this critical public health issue. For further information please contact Barrett Thornhill at bthornhill@antimicrobialalliance.com.

Sincerely,

Antimicrobial Innovation Alliance

Achaogen

AstraZeneca

Astellas Pharma US

Forest Laboratories

GlaxoSmithKline

Merck & Co.