



June 28, 2018

Washington, DC-- The Antimicrobial Innovation Alliance (AIA), a diverse coalition of pharmaceutical innovators, applauds Representatives John Shimkus and Tony Cardenas on the introduction of the Re-Valuing Anti-Microbial Products (REVAMP) Act of 2018.

Antimicrobial resistance (AMR) has emerged as a significant threat to global health security that is expected to undermine the achievements of modern medicine. New antimicrobials are urgently needed, however, there are relatively few in development. Over the past two decades, there has been a considerable decline in the number of companies conducting antibiotic and antifungal R&D due to the significant scientific, regulatory, and economic challenges specific to this therapeutic area.

All major research and pharmacoeconomic analyses, including several reports developed by the U.S. Government, have concluded that:

- 1) The market has failed for critical need antimicrobials (antibiotics that address priority pathogens posing the greatest public health threat for antimicrobial resistance).
- 2) Market-based awards substantially improving the valuation of new agents are necessary.
- 3) New antimicrobials should be protected with appropriate stewardship guardrails.

Market entry awards have been proffered recently by numerous leading stakeholders, including Chatham House, DRIVE-AB, The Review on Antimicrobial Resistance, the German Global Union for Antibiotics Research and Development, and the Duke-Margolis Center for Health Policy. Market entry awards, in addition, have support from leading stakeholders such as the Infectious Diseases Society for America and a large community of concerned patient and provider groups. The most impactful entry award incentive mechanism, which eliminates some of the concerns of other entry awards, is the Transferable Conveyance Award.

Today's REVAMP legislation provides such awards for priority antimicrobials, applies prudent guardrails and appropriate use mechanisms, and additionally provide additional funds for early stage R&D.

"There is no greater threat to the health and economic welfare of Americans than the relentless growth of MDR microorganisms. In my years of experience in the pharmaceutical industry, I have never seen such a dire threat to human health receive so little attention," said **Ted Schroeder, CEO, Zavante Therapeutics**.

Blake Wise, CEO, Achaogen added, "We believe that a meaningful pull incentive like transferable conveyance awards, as proposed in the REVAMP legislation, would have a massive impact on the sustainability of the antibiotics marketplace and the ability to continue to address this public health crisis."

Zach Zimmerman, CEO, Forge Therapeutics satted, "Drug discovery is like running a marathon where early-stage investment provides the horsepower to get from the Starting Line to Mile 5; but how to get to Mile 26? In any other drug development 'marathons' there would be a prize at the end of the race for the winners...a medal, a trophy, patients who need the drug and payors to support sales. Because of these potential profits, later-stage investors will provide to companies the sought-after capital needed to cross the Finish Line. The 'antibiotic' marathon is different...there is no trophy for the winners."

And **Kevin Outterson, Executive Director, CARB-X** program emphasized, "For the fight against superbugs, this is the most important legislation in more than a generation. Dozens of small research companies with outstanding products struggle mightily to keep the lights on in their labs. With this bill, a vital scientific sector is transformed overnight."

Established to address the unique challenges facing the research, development and commercialization of antimicrobial products, the AIA works with policymakers and others to address the threat of antibacterial resistance, now and in the future. Its members include Achaogen, Allergan, Astellas US, Basilea, Forge Therapeutics, Genentech, Johnson& Johnson, Pfizer, and Zavante. For more information or inquiries, please contact Barrett Thornhill, Executive Director, at bthornhill@antimicrobialalliance.com.