



IDSAs

Infectious Diseases Society of America

June 29, 2018

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United States House of Representatives
Energy & Commerce Committee
2217 Rayburn House Office Building
Washington, DC 20515

The Honorable Tony Cárdenas
United States House of Representatives
Energy & Commerce Committee
1510 Longworth House Office Building
Washington, DC 20515

Dear Representatives Shimkus and Cardenas,

The Infectious Diseases Society of America (IDSA) thanks you for introducing the Re-Valuing Anti-Microbial Products (REVAMP) Act. We are pleased to offer our support for this legislation that would provide an important economic incentive for the research and development of urgently needed new antibiotics. IDSA represents over 11,000 infectious diseases physicians and scientists, and our members are seeing increasing numbers of patients whose infections are extremely difficult or impossible to treat due to antimicrobial resistance and a lack of new antibiotics.

As you likely know, the Centers for Disease Control and Prevention estimate that at least 2 million Americans are sickened by antibiotic-resistant bacteria every year, and at least 23,000 die. The availability of safe and effective antibiotics has made possible tremendous advances in medical care, including solid organ and bone marrow transplants, cancer chemotherapy, the care of preterm infants, joint replacements, and other complex surgeries. However, as antimicrobial resistance increases and antibiotic R&D dwindles, these medical advances are jeopardized as once treatable infections threaten to become deadly.

We greatly appreciate congressional efforts to incent antibiotic R&D, and the Generating Antibiotic Incentives Now (GAIN) Act, the Antibiotic Development to Advance Patient Treatment (ADAPT) Act, and increased funding for the National Institute of Allergy and Infectious Diseases (NIAID) and the Biomedical Advanced Research and Development Authority (BARDA) have made important progress. Unfortunately, the antibiotic pipeline remains insufficient to meet patient needs. Despite regulatory improvements and push incentives that help reduce development costs, it is extremely challenging to secure private sector investment in antibiotic R&D with little to no opportunity for a return on that investment.

The stewardship or appropriate use of antibiotics is essential to maintain their clinical utility and limit the development of resistance. As a result, traditional models that rely upon high sales volume of a new drug to provide a return on investment are not feasible for antibiotics. IDSA has called for an incentive that would de-link the return on investment and the sales and use of an antibiotic meeting an unmet need. Your legislation provides one option for such an incentive by authorizing conveyed exclusivity extensions through which the developer of a new antibiotic that addresses an unmet medical need and is licensed after January 1, 2023 may transfer 12 months of that antibiotic's exclusivity to a different product. We are pleased to support your efforts.

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We also greatly appreciate that your bill would require companies receiving an exclusivity conveyance award to promote antibiotic stewardship and the development of antimicrobial susceptibility test devices as well as donate 5 percent of the value of their award to the Foundation for the National Institutes of Health for antimicrobial research.

Once again, we greatly appreciate your leadership on the urgent need for new antibiotics to address multidrug-resistant infections. We look forward to working with you on this important public health issue.

Sincerely,

A handwritten signature in black ink, appearing to read "Paul G. Auwaerter". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Paul G. Auwaerter, MD, MBA, FIDSA
President, IDSA