



July 17, 2018

The Honorable Greg Walden  
Chairman  
Committee on Energy & Commerce  
2185 Rayburn House Office Building  
United States House of Representatives  
Washington, DC 20515

The Honorable Frank Pallone, Jr.  
Ranking Member  
Committee on Energy & Commerce  
237 Cannon House Office Building  
United States House of Representatives  
Washington, DC 20515

Dear Representatives Walden and Pallone:

On behalf of the Biotechnology Innovation Organization (BIO), I am writing to express our support for the Re-Valuing Antimicrobial Products Act of 2018 (REVAMP Act, H.R.6294). The REVAMP Act has the potential to stimulate much needed investment for innovative medicines that can help patients suffering the growing threat of antimicrobial resistance (AMR). While no legislation is perfect, BIO and its member companies stand ready to work with you to ensure that the REVAMP Act has a meaningful impact on the antimicrobial pipeline.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members are committed to investing in, developing, and delivering innovative vaccines, therapeutics, and diagnostic tools that are transforming how we protect, treat and cure people from devastating infectious diseases. As a signatory of the 2016 Davos Declaration on AMR and member of the AMR Industry Alliance, BIO is fully committed to addressing the rise of AMR infections by promoting antimicrobial R&D, stewardship, and access.

AMR represents a serious threat to the public health, food safety, and national security of the American people. Resistance reduces the effectiveness of treatments for infectious diseases and jeopardizes health care gains that rely on the ability to effectively treat and prevent bacterial infections, such as organ transplantation, cancer chemotherapy, and major surgery. Resistant pathogens are also prime candidates to be weaponized by our Nation's enemies—both state and non-state actors. Further, wounds and burns resulting from a mass casualty event can also become quickly infected, and AMR can make those infections much more challenging to treat.

The Centers for Disease Control and Prevention (CDC) estimates that annually 2 million people suffer from resistant infections, with at least 23,000 dying as a direct result. The Review on Antimicrobial Resistance estimates that unless action is taken, by 2050, AMR could take 10 million lives globally each year; the World Bank estimates that drug-resistant infections have the potential to cause economic damage similar to—and likely worse than—that caused by the 2008 financial crisis. In addition to efforts to conserve our dwindling arsenal of antimicrobials, there is an urgent need for new medicines to help treat and prevent resistant infections.

Unfortunately, few products are under development to address AMR. Key groups, including the Presidential Advisory Committee on Combating Antibiotic-Resistant Bacteria (PACCARB), have independently assessed the pipeline and have concluded that the economic model is insufficient to ensure the availability of new products to help address the rise of drug resistance. The PACCARB and others have recommended that the U.S. government implement a suite of incentives, both

those that help address R&D challenges and, more importantly, those that address marketplace challenges. The REVAMP Act represents an opportunity for an incentive that helps to address both the R&D challenges and the market challenges by providing a return on antimicrobial R&D that is de-linked from sales. The legislation also includes key mechanisms to ensure appropriate use of these products as well as generate funds to help support additional antimicrobial R&D.

If these underlying challenges are not addressed, we run the risk of continued decline in investment in the antimicrobial space and an antimicrobial pipeline that cannot adequately address the increase in resistant infections. We believe there is an urgent need to reinvigorate the pipeline to address AMR and biodefense priorities.

BIO appreciates your interest in addressing the issues of antimicrobial resistance and supporting the development of novel antimicrobial products. We support the passage of REVAMP as part of the reauthorization of the Pandemic All Hazards Preparedness Act. We look forward to further improving the REVAMP Act to ensure that Americans are safe from the threat of AMR.

With sincerest regards,

A handwritten signature in black ink that reads "Jim Greenwood". The signature is written in a cursive, flowing style with a large initial "J".

James C. Greenwood  
President and CEO