

The Honorable Greg Walden
Chairman
Committee on Energy & Commerce
United States House of Representatives

The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy & Commerce
United States House of Representatives

July 12, 2018

The undersigned organizations, representing healthcare providers, hospitals, industry, patients, pharmacists, public health experts, scientists, and advocates are deeply concerned about the serious threat antimicrobial resistant (AMR) pathogens pose to American health and national security, and are alarmed by the insufficient number of new antimicrobials, vaccines, and diagnostics to combat that threat. Without novel treatments antimicrobial resistance will reduce the effectiveness of treatments for infectious diseases and jeopardizes health care gains to society that rely on the ability to effectively treat and prevent bacterial infections such as organ transplantation, cancer chemotherapy, caesarian sections, and major surgery. We are writing to express our support for REVAMP: Re-Valuing Antimicrobial Products of 2018 (H.R.6294) and call for it to be included in the reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA) to ensure Americans are safe from increasing AMR and the threat posed by weaponized pathogens.

AMR is one of the world's most significant health threats. According to the Centers for Disease Control and Prevention, the annual U.S. impact from drug resistant infections includes over 2 million illnesses, 23,000 deaths, over \$30 billion in excess direct health expenditures, with another \$35 billion in other societal and economic costs. By 2050 it has been predicted that there will be 10 million deaths a year due to multi-drug resistant infections. The World Bank estimates that this could result in a 3.8 percent decrease in global annual gross domestic product.

Furthermore, AMR poses a significant threat to our national security. Resistant pathogens affect soldiers injured on the battlefield, making amputation or death more likely. Between 2004 and 2009, more than 3,300 American soldiers in Iraq and Afghanistan became severely ill from a single resistant pathogen—*Acinetobacter*, which is becoming increasingly resistant. Of great concern is that resistant pathogens can be weaponized to attack the country. Studies have concluded that the aerosolized release of a weaponized, resistant pathogen in just a single incident of bioterrorism in the Washington, DC area would result in a death toll of more than 3 million. The death toll from a coordinated bioterrorist attack using a weaponized resistant pathogen would be many magnitudes higher. Even non-weaponized AMR puts our health security at risk, both within the US and globally. An outbreak of a serious resistant infection with limited or no treatment options could overwhelm health systems, harm economies and even destabilize communities or entire countries.

We greatly appreciate that the Biomedical Advanced Research and Development Authority (BARDA) is already providing essential support for antimicrobial R&D. However, significant unmet needs persist and new incentives are necessary to ensure that our nation is prepared to respond to the AMR threat.

New antimicrobials are urgently needed to protect the country, however, there are relatively few in development. According to Pew Charitable Trusts it has been decades since a truly new innovative class of antibiotics has made it to market. A 2017 report by the World Health Organization found only 8 products in development are classed as innovative treatments that will add value to the current antibiotic treatment arsenal. In June 2018 the United Nations published a discussion paper

calling on governments to develop incentives that are sustainable and able to support appropriate use of antibiotics.

Incentives that provide a return on investment for antimicrobial R&D that is de-linked from the sales and use of antimicrobial drugs have been proposed by numerous leading stakeholders, including the G7, IDSA, The Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, the President's Council of Advisors on Science and Technology, Chatham House, The Review on Antimicrobial Resistance, and the Duke-Margolis Center for Health Policy. The REVAMP legislation provides such an incentive for priority antimicrobials, applies prudent guardrails and appropriate use mechanisms, and provides additional funds for early stage R&D. The 'exclusivity conveyance' does not require significant upfront government funding or annual appropriations, thus not impacting existing public health or biodefense spending. The incentive addresses the economic imbalance by allowing the sponsor of a subset of priority antibiotics to transfer up to 12 months of exclusivity to another drug product (the "recipient drug"). The revenues from the conveyance provide a sustainable incentive that compensates for the minimal return on investment of the antimicrobial drug.

We thank you for your work on bioemergency preparedness issues. Due to the absence of new antibiotics, vaccines and other innovative therapies in development there is an impending crisis that requires immediate action to mitigate. As such we strongly urge you to include REVAMP in the reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA) to ensure Americans are safe from increasing AMR and the threat posed by weaponized pathogens. We look forward to working with you as the committee continues to advance the PAHPA reauthorization bill.

Sincerely,

Accelerate Diagnostics, Inc.

Achaogen

Aequor, Inc.

Alliance for the Prudent Use of Antibiotics

American Academy of Allergy, Asthma, and Immunology

American Association of Bovine Practitioners

American Public Health Association

Antimicrobial Innovation Alliance

Antimicrobials Working Group (Amplify Pharmaceuticals, Aridis Pharmaceuticals, Arsanis Inc., Cidara Therapeutics Inc., ContraFect Corporation, Entasis Therapeutics Inc., Iterum Therapeutics Ltd., Melinta Therapeutics Inc., Motif Bio plc, Nabriva Therapeutics US Inc., Paratek Pharmaceuticals Inc., SCYNEXIS Inc., Spero Therapeutics, Inc., T2 Biosystems Inc., Theravance Biopharma U.S. Inc., Viamet, Vical Incorporated, and Zavante Therapeutics Inc.)

Association for Professionals in Infection Control and Epidemiology

Center for Foodborne Illness Research & Prevention

Emory Antibiotic Resistance Center

F2G, Ltd.

Forge Therapeutics

GlaxoSmithKline

Infectious Diseases Society of America

Institute for Clinical Pharmacodynamics

Janssen

Making-A-Difference in Infectious Diseases

March of Dimes
National Association of Pediatric Nurse Practitioners
National Athletic Trainers' Association
Natureza Products Inc.
Nexgen Biosciences
Octagon Therapeutics
Sample6
Sequella, Inc.
Society of Critical Care Medicine
Society of Infectious Diseases Pharmacists
Spero Therapeutics
The Fecal Transplant Foundation
The Gerontological Society of America
VenatoRx Pharmaceuticals