

May 24, 2017

The Honorable Greg Walden
Chairman
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
2322A Rayburn House Office Building
Washington, DC 20515

Dear Chairman Walden and Ranking Member Pallone,

Antimicrobial resistance (AMR) is one of the world's most significant public health threats, and international bodies from the United Nations¹ and World Health Organization² to governments of the United Kingdom³, Germany⁴ as well as our Centers for Disease Control and Prevention⁵ agree that we are woefully unprepared.

According to a leading study commissioned by the U.S. Department of Health and Human Services, "At least 2 million people in the U.S. acquire serious infections with bacteria that are resistant to one or more of antibacterial drugs designed to treat it. Despite the potential of new antibacterial products to reduce the social burden associated with resistant infections, development of antibacterials has been limited by insufficient return to capital invested in development of these products."⁶ The Obama Administration's Council of Advisors on Science and Technology also reported that "Overall, the current pipeline of antibiotic development is inadequate to combat resistance... Major economic incentives will be necessary to substantially expand private investment in developing urgently needed antibiotics, including drugs to address evolving future needs."⁷ In February 2017, W.H.O. assistant director general said if changes are not made to the marketplace, new antimicrobial products will not be developed in time to address the crisis. And just days ago, the Health Ministers of the G20 also acknowledged the crisis and called for "reactivating the R&D pipeline through incentive mechanisms that avoid the reliance on high price/volume combinations."⁸

To answer this global 'call to arms,' we urge this Committee to support the Re-Valuing Anti-Microbial Products (REVAMP) Act of 2017 that provides exclusivity conveyance awards to incent the development of unmet medical need antimicrobial products. Properly designed and implemented, the revenue generated from such an award can compensate antimicrobial drug

¹ <http://www.un.org/pga/71/event-latest/high-level-meeting-on-antimicrobial-resistance/>

² <http://www.who.int/antimicrobial-resistance/en/>

³ <https://amr-review.org/>

⁴ http://www.bundesgesundheitsministerium.de/fileadmin/Dateien/5_Publikationen/Gesundheit/Berichte/GUARD_Follow_Up_Report_Full_Report_final.pdf

⁵ <https://www.cdc.gov/drugresistance/>

⁶ <https://aspe.hhs.gov/report/analytical-framework-examining-value-antibacterial-products>

⁷ https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/PCAST/pcast_carb_report_sept2014.pdf

⁸ https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/G/G20-Gesundheitsministertreffen/G20_Health_Ministers_Declaration_engl.pdf

developers for the minimal return on investment these products present. The Infectious Disease Society of America first raised the concept of exclusivity awards over 10 years ago. Considering the almost-dry pipeline of antimicrobial products aimed at the most serious infections, we cannot let another decade go by without substantial federal action.

We thank you for your support on these important issues and look forward to working with you to counter the effects of AMR on our public health.