

June 7, 2016

United States Senate  
Washington, DC 20510

RE: Bennet/Hatch/Blumenthal/Kirk S.AMDT. 4422 to S. 2943, the National Defense Authorization Act (NDAA) of Fiscal Year 2017 related to antibiotic development to address unmet need

Dear Senator:

The undersigned organizations write to urge your support of S.AMDT. 4422 filed by Senators Bennet (D-CO), Hatch (R-UT), Blumenthal (D-CT), and Kirk (R-IL) to S. 2943, the National Defense Authorization Act (NDAA) of Fiscal Year 2017. The amendment mirrors the language of S. 185, the bipartisan Promise for Antibiotics and Therapeutics for Health (PATH) Act, as amended and favorably reported out of the Senate Health, Education, Labor and Pensions (HELP) Committee on April 6, 2016.

Recently, U.S. Department of Defense (DoD) researchers found that a Pennsylvania woman carried a strain of *E. coli* resistant to colistin, an antibiotic of ‘last resort.’ This new mechanism for bacterial resistance was discovered last year by researchers in China. Since then, researchers have identified the colistin-resistance-gene, MCR-1, in 19 additional countries, now including the United States. They have found the gene in both human and animal specimens.

This is a sharp reminder that antibiotic resistance is outpacing antibiotic development. No new class of antibiotic has been discovered that made it to a patient’s bedside in nearly 30 years, and an analysis of the antibiotic pipeline by the Pew Charitable Trusts shows few drugs in development for the most serious microbial threats, such as deadly bacterial infections caused by *Acinetobacter* and *Pseudomonas aeruginosa*.

Economic and regulatory challenges have slowed antibiotic research and development (R&D). Many major pharmaceutical companies have shifted their R&D investments from antibiotics to more economically viable therapeutic areas. However, there is some reason for cautious optimism. In 2012, Congress passed the Generating Antibiotics Incentives Now (GAIN) act, which gave additional exclusivity for antibiotics to treat serious and life threatening infections. Companies have cited GAIN as a reason they have gotten into the antibiotics market. And earlier this year at the World Economic Forum in Davos, Switzerland, over 80 drug companies committed to addressing antibiotic resistance by improving antibiotic stewardship and investing in research and development of new antibiotics.

These are glimmers of hope. Unfortunately, they are insufficient to ensure that patients have access to the drugs they need most—drugs to treat serious and life threatening infections for which there are few or no other options. The PATH Act would be an important complement to GAIN by facilitating the development of this category of drugs.

The PATH Act would establish a new limited population antibacterial drug (LPAD) approval pathway for antibiotics to treat serious or life-threatening infections for which there exists an unmet medical need. A new pathway is required because it is often not possible to develop antibiotics for some of the most serious infections using traditional, large clinical trials due to the limited numbers of patients in whom these infections currently occur. PATH would also put in place safeguards to guide the appropriate use of LPAD drugs — thereby optimizing patient care and limiting the development of resistance. Importantly, any drug

approved under this new pathway must still meet existing FDA standards of evidence for safety and effectiveness for the indicated limited population.

As you may know, language very similar to the PATH Act was included in the 21st Century Cures Act, which was passed by an overwhelming bipartisan majority (344-77) in the House of Representatives on July 10, 2015. The PATH Act's approach was also recommended by the President's Council of Advisors on Science and Technology (PCAST) in its September 2014 report on antibiotic resistance.

The Senate has an opportunity to join the House to make a meaningful difference in the fight against antibiotic-resistant bacteria. We urge you to capitalize on this opportunity and pass the Bennet/Hatch/Blumenthal/Kirk PATH amendment.

Sincerely,

Alliance for Aging Research  
Alliance for the Prudent Use of Antibiotics  
American Academy of Allergy, Asthma & Immunology  
American Academy of Pediatrics  
American Association of Bovine Practitioners  
American Association of Swine Veterinarians  
American Gastroenterological Association  
American Public Health Association  
American Society for Microbiology  
American Society of Transplant Surgeons  
American Thoracic Society  
Association for Professionals in Infection Control and Epidemiology  
Association of State and Territorial Health Officials  
Cempra, Inc.  
Center for Foodborne Illness Research & Prevention  
Dignity Health  
Emory Antibiotic Resistance Center  
HIV Medicine Association  
Immune Deficiency Foundation

Infectious Diseases Society of America  
Making-A-Difference in Infectious Diseases  
March of Dimes  
Musculoskeletal Infection Society  
National Association of County and City Health Officials  
National Association of Pediatric Nurse Practitioners  
National Athletic Trainers' Association  
ONCORD, Inc.  
Pediatric Infectious Diseases Society  
Research!America  
Society for Healthcare Epidemiology of America  
Society of Critical Care Medicine  
Society of Infectious Diseases Pharmacists  
Spero Therapeutics  
TB Alliance  
The American Association of Immunologists  
The Fecal Transplant Foundation  
The Pew Charitable Trusts  
Theravance Biopharma  
Trust for America's Health  
UPMC Center for Health Security