

September 6, 2016

The Honorable Mitch McConnell
Majority Leader
U.S. Senate
Washington, D.C. 20510

The Honorable Harry Reid
Minority Leader
U.S. Senate
Washington, D.C. 20510

The Honorable Lamar Alexander
Chairman, Committee on
Health, Education, Labor & Pensions
U.S. Senate
Washington, D.C. 20510

The Honorable Patty Murray
Ranking Member, Committee on
Health, Education, Labor & Pensions
U.S. Senate
Washington, D.C. 20510

Dear Senators McConnell, Reid, Alexander and Murray:

The undersigned organizations write to urge you to pass S. 185, the bipartisan Promise for Antibiotics and Therapeutics for Health (PATH) Act, this year in order to 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.

Antibiotics are fundamental to modern medicine, essential for protecting vulnerable patients receiving chemotherapy or being treated in intensive care units. But the proliferation of antibiotic-resistant bacteria – a result of decades of overuse combined with a lack of new drug development and innovation – threatens to bring us to a “post-antibiotic” world in which even the most simple surgical procedure could have deadly consequences.

Already, resistance threatens the continued efficacy of our current arsenal of antibiotics with important consequences. The Centers for Disease Control and Prevention estimate that each year at least 2 million people are infected with resistant bacteria and at least 23,000 people die each year as a result.

In just the last few months we have seen an alarming development in antibiotic resistance. In May, U.S. Department of Defense researchers identified a patient in Pennsylvania infected with a strain of bacteria carrying a new antibiotic resistance mechanism, MCR-1. This rapidly spreading mechanism – first identified in China in November of 2015 but now present globally – confers resistance to colistin, a “last resort” antibiotic.

The discovery of easily-transferable resistance to an antibiotic of last resort highlights the urgent need to take a multi-pronged approach to combatting antibiotic resistance which includes optimizing antibiotic use while simultaneously prioritizing the discovery and development of new antibiotics. It has been over 30 years since a new class of antibiotic was discovered that made it to a patient’s bedside. An analysis of the antibiotic pipeline by the Pew Charitable Trusts shows that few of the drugs in development will address the most serious microbial threats, such as deadly bacterial infections caused by *Acinetobacter* and *Pseudomonas aeruginosa*.

Economic and regulatory challenges continue to stunt antibiotic development activities. Many of the companies that once led the research and development of new antibiotics have since shifted their scientific resources to more economically viable therapeutic areas. However, there are many reasons to be cautiously optimistic about antibiotic development. 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 stated that GAIN helped convince them to enter or return to the antibiotics market.

Momentum is building as major international groups, notably the Group of 7 (G7), and World Health Organization have expressed their commitment to take substantive action to tackle the problem of antibiotic resistance. At the UN General Assembly in September, heads of state will gather to make a political declaration

regarding action on AMR – only the third time in history that a high level UN declaration will focus on public health.

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 development of these vital drugs.

The PATH Act would establish a new limited population antibacterial drug approval pathway for antibiotics to treat serious or life-threatening infections for which there exists an unmet medical need. These infections currently affect a limited number of patients, making the process of conducting traditional, large clinical trials all but impossible. The new pathway proposed by PATH is necessary to develop novel antibiotics and bring them to the patients that need them most. 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 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 the House passed by an overwhelming bipartisan majority on July 10, 2015. The PATH Act’s approach was also recommended by the President’s Council of Advisors on Science and Technology and draws support from a broad range of stakeholders, including public health groups, provider organizations, and pharmaceutical companies.

The Senate has an opportunity to join the House in making a meaningful difference in the fight against antibiotic-resistant bacteria. Given the development of highly transferrable antibiotic resistance this year, we urge you to take action on this important legislation this year in order to help bring new antibiotics to patients in severe need.

Sincerely,

Alliance for Aging Research
Alliance for the Prudent Use of Antibiotics
American Academy of Pediatrics
American Association of Bovine Practitioners
American Public Health Association
American Society for Microbiology
American Society of Transplant Surgeons
American Thoracic Society
American Urological Association
Antimicrobials Working Group (Amplix
Pharmaceuticals, Arsanis, Cempra, Cidara
Therapeutics, Contrafect, Melinta, Nabriva, Paratek,
Scynexis, Theravance, Viamet, Iterum Therapeutics)
Association for Professionals in Infection Control
and Epidemiology
Association of American Veterinary Medical
Colleges
Association of State and Territorial Health Officials
BEAM Alliance
Center for Foodborne Illness Research & Prevention
Da Volterra
Dignity Health
Emory Antibiotic Resistance Center
Friends of Cancer Research
GlaxoSmithKline

HIV Medicine Association
Infectious Diseases Society of America
Making-A-Difference in Infectious Diseases
March of Dimes
Michigan Antibiotic Resistance Reduction Coalition
Microbion Corporation
Morphochem, Inc.
National Association of County and City Health
Officials
National Association of Pediatric Nurse Practitioners
National Athletic Trainers' Association
NovaDigm Therapeutics, Inc.
ONCORD, Inc.
Pediatric Infectious Diseases Society
Research!America
Society for Healthcare Epidemiology of America
Society of Critical Care Medicine
Society of Infectious Diseases Pharmacists
The American Association of Immunologists
The Fecal Transplant Foundation
The Flag and General Officers Network
The Pew Charitable Trusts
Theravance Biopharma
Trust for America’s Health