

February 23, 2016

The Honorable Lamar Alexander
Chairman
Committee on Health, Education, Labor,
and Pensions (HELP)
U.S. Senate
455 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor,
and Pensions (HELP)
U.S. Senate
154 Russell Senate Office Building
Washington, DC 20510

Dear Chairman Alexander and Ranking Member Murray:

The undersigned organizations thank you for the Senate HELP Committee's longstanding interest in addressing antimicrobial resistance and ask that you include S. 185, the bipartisan Promise for Antibiotics and Therapeutics for Health (PATH) Act, in your upcoming mark-up of legislation to encourage biomedical innovation.

In November 2015, researchers in China discovered a new mechanism for bacterial resistance to our "last-resort" antibiotic, colistin. Since then, researchers have identified the colistin-resistant-gene, MCR-1, in 18 additional countries and this number is likely to grow. 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, in large part due to the leadership of the HELP committee, 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 just last month 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 move PATH to the Senate floor.

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 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
HIV Medicine Association
Immune Deficiency Foundation
Infectious Diseases Society of America
Making-A-Difference in Infectious Diseases
March of Dimes
National Association of Pediatric Nurse Practitioners
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 Pew Charitable Trusts
Theravance Biopharma
Trust for America's Health
UPMC Center for Health Security