

January 30, 2015

The Honorable Orrin Hatch
United States Senate
104 Hart Senate Office Building
Washington, DC 20510

The Honorable Michael Bennet
United States Senate
458 Russell Senate Office Building
Washington, DC 20510

Dear Senators Hatch and Bennet:

The undersigned organizations represent healthcare providers, hospitals, pharmacists, clinical laboratory scientists and medical microbiologists, public health experts, patients and advocates. We write to express support for S. 185, the Promise for Antibiotics and Therapeutics for Health (PATH) Act, legislation to 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. Without such a pathway, we fear that antibiotic research and development (R&D) will continue to struggle, and that patients will continue dying without new treatments.

Antibiotic resistance remains a serious patient safety, public health, and national security concern. As a 2014 report by the President's Council of Advisors on Science and Technology (PCAST) noted, the development of antibiotic resistance is occurring at an alarming rate and far outpacing the development of new antibiotics. As a result, increasing numbers of patients are contracting serious and even deadly infections that are difficult and sometimes impossible to treat, resulting in longer hospital stays, complications of other medical treatments such as surgery or chemotherapy, and even deaths. Patients with weakened immune systems, such as those with HIV/AIDS, preterm infants, cancer patients, transplant patients, the elderly, or patients treated in intensive care units are at heightened risk, but even healthy young people are contracting and dying from serious, antibiotic resistant infections.

Antibiotic development has dwindled, with many pharmaceutical companies leaving this market. One key reason has been the lack of a clear, feasible regulatory pathway for Food and Drug Administration (FDA) approval of a new antibiotic for some of the most serious infections caused by multidrug-resistant (MDR) pathogens. It is often not feasible 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. PCAST explicitly recommended the creation of a new limited population pathway for antibiotics to treat a serious or life-threatening infection in order to meet an unmet medical need. This is exactly what the PATH Act would do.

Importantly, any drug approved under this new pathway must still meet the Food and Drug Administration's (FDA) standards of evidence for safety and effectiveness for the indicated limited population. Further, the PATH Act contains several important provisions to help guide the appropriate use of antibiotics approved under this new pathway. Appropriate use is critical to deliver optimal patient care while limiting the likelihood of antibiotic resistance developing to these new antibiotics.

As organizations dedicated to patient care and public health, we thank you for your leadership on this critical issue. We look forward to working with you to advance the PATH Act.

Sincerely,

Accelerate Diagnostics Inc.
Alliance for Aging Research
Alliance for the Prudent Use of Antibiotics
American Academy of Pediatrics
American College of Preventive Medicine
American College of Rheumatology
American Gastroenterological Association
American Pharmacists Association
American Public Health Association
American Society for Microbiology
American Thoracic Society
American Urological Association
Antibiotics Working Group (Cempra, Durata Therapeutics, Optimer Pharmaceuticals, Melinta, The Medicines Company and Theravance)
Association for Professionals in Infection Control and Epidemiology
California Tuberculosis Controllers Association
Cempra, Inc.
Center for a Livable Future
Center for Foodborne Illness Research & Prevention
DaVolterra
Dignity Health
Harm Reduction Coalition
Health Care Without Harm
HIV Medicine Association
Infectious Diseases Society of America
Michigan Antibiotic Resistance Reduction Coalition
Microbion Corporation
National Association of County and City Health Officials
National Association of Pediatric Nurse Practitioners
National Foundation for Infectious Diseases
National Tuberculosis Controllers Association
ONCORD, Inc.
Pediatric Infectious Diseases Society
Society for Healthcare Epidemiology of America
Society of Critical Care Medicine
Society of Infectious Diseases Pharmacists
The Medicines Company
The Pew Charitable Trusts
Trust for America's Health
UPMC Center for Health Security