

July 28, 2015

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

The Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor,
and Pensions
U.S. Senate
428 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Alexander and Ranking Member Murray:

The undersigned organizations represent healthcare providers, hospitals, pharmacists, scientists and microbiologists, public health experts, patients and advocates. We write to urge you to include S. 185, the bipartisan Promise for Antibiotics and Therapeutics for Health (PATH) Act, in broader legislation you are developing for the Innovation for Healthier Americans initiative.

We are deeply concerned about the alarming rise of antibiotic resistance and the insufficient number of new antibiotics to treat multidrug resistant infections. 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 pathogens. 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.

The PATH Act would help address multiple facets of this complex problem by (1) establishing 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, and (2) putting in place safeguards to guide the appropriate use of these drugs — thereby optimizing patient care and limiting the development of resistance. 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. 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.

In 2013, a number of stakeholders, including provider groups, public health groups, and companies came together to develop a set of [core principles for an LPAD pathway](#). These principles include that drugs approved under the pathway bear distinct labeling, that their use be monitored, and that the

pathway not attempt to regulate the practice of medicine. We appreciate that the PATH Act is consistent with all of the principles.

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. 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.

Sincerely,

Alliance for Aging Research
Alliance for the Prudent Use of Antibiotics
American Academy of Allergy, Asthma & Immunology
American Academy of Pediatrics
American College of Rheumatology
American Gastroenterological Association
American Pharmacists Association
American Public Health Association
American Society for Microbiology
American Society of Transplant Surgeons
American Thoracic Society
Antibiotics Working Group (Cempra, Durata Therapeutics, Optimer Pharmaceuticals, Melinta, The Medicines Company and Theravance)
Association for Professionals in Infection Control and Epidemiology
Association of State and Territorial Health Officials
Cempra, Inc.
Center for a Livable Future
Dignity Health
Health Care Without Harm
HIV Medicine Association
Infectious Diseases Society of America
Making-A-Difference in Infectious Diseases
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 Disease Pharmacists
The Pew Charitable Trusts
Theravance Biopharma
Trust for America's Health
UPMC Center for Health Security