

Support Bennet/Hatch/Blumenthal/Kirk Antibiotic Amendment #4422 To S. 2943, National Defense Authorization Act (NDAA) of Fiscal Year 2017

The Bennet/Hatch/Blumenthal/Kirk S.AMDT. 4422 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. Ensuring a robust antibiotic pipeline is important for everyone, and in particular for those at higher risk for contracting infections, including our military men and women and those with compromised immune systems. The PATH Act would incentivize antibiotic research and development (R&D) by addressing a regulatory hurdle related to clinical trial design for antibacterial drugs that are intended for treatment of a serious or life-threatening disease or condition in a limited population of patients for which there is an unmet medical need.

BACKGROUND

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.

According to the CDC, approximately 23,000 Americans will die this year due to antibiotic-resistant infections. The economic costs of antibiotic resistance are high as well. Drug-resistant bacterial infections cost the U.S. health care system an estimated \$20 billion annually (including 8 million additional hospital days) and \$34 billion in societal costs.

Military personnel are deployed around the world and therefore potentially encounter a broader range of bacteria, and resistance, than more stationary civilian populations. Soldiers and veterans are at particular risk, as multidrug resistant pathogens can easily infect combat wounds and burns, leading to increased risk of limb loss, sepsis and even death. The DoD is supporting research to help develop new antibiotics, but policies such as PATH are needed to ensure that new drugs have a feasible and appropriate path to FDA approval.

Antibiotic development is often not economically feasible for companies because these drugs must be used infrequently to protect against the development of resistance, are often priced low, and are used for short durations. In 1990, there were almost 20 pharmaceutical companies with large antibiotic research and development (R&D) programs. Today, there are only two or three large companies with strong and active programs and only a small number of companies have more limited programs. To help reinvigorate the pipeline, the President's Council of Advisors on Science and Technology (PCAST) recommended an approach like PATH in its 2014 *Report to the President on Combating Antibiotic Resistance*.

SUMMARY

The PATH Act builds on the Generating Antibiotic Incentives Now (GAIN) Act, enacted by the 112th Congress. PATH would help to advance antibiotic drug development by establishing a new Food and Drug Administration (FDA) pathway for antibiotics that permits the agency to approve drugs aimed at treating serious or life-threatening infections in limited populations who currently have few or no treatment options. This will greatly enhance the development of new treatments, which bolsters public health while retaining FDA standards of evidence for safety and effectiveness. The PATH Act would encourage surveillance and stewardship activities, which are also critical to address antimicrobial resistance.

CONTACT

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THREAT OF ANTIMICROBIAL RESISTANCE TO THE U.S. MILITARY

The threat of multidrug-resistant infections to the U.S. military has been documented to Congress via expert testimony:

- **“The increase in MDRO [multidrug-resistant organism] infections has resulted in a shortage of safe and effective antibiotics. . . . While both civilian and DOD [Department of Defense] hospitals are dealing with this challenging epidemic, the demographics of patients with MDRO infections are different. Most U.S. hospitals have reported these problems among patients with an increased length of stay, frequently the elderly, with multiple complicated medical problems and usually in an intensive care unit. Military hospitals experience cases of MDRO infections occurring in the younger, combat-injured patients. MDROs complicate chronic skin and soft tissue infections, osteomyelitis, and, in some of the injured, led to increased limb loss, sepsis, and death.”**
— Witness Statement of Colonel (Dr.) James Collier and Lieutenant Colonel (Dr.) Michael Forgione, United States Air Force, before the House Armed Services Subcommittee on Oversight and Investigations, September 29, 2010
- **“According to available data from the Department of Defense, approximately 3,300 service members that were treated in military treatment facilities during 2004-2009 had Acinetobacter infections.”**
— Memorandum on DOD's Response to Multidrug-resistant Infections in Military Hospitals, Subcommittee on Oversight and Investigations, House Committee on Armed Services, U.S. House of Representatives, December 6, 2010

SUPPORT -- The following organizations have written Congress in support of passage of the PATH Act:

American Logistics Association	Association for Professionals in Infection Control and Epidemiology
American Military Retirees Association	Association of State and Territorial Health Officials
American Military Society	Cempra, Inc.
American Retirees Association	Center for Foodborne Illness Research & Prevention
Army Navy Union	Dignity Health
Association of the United States Navy	Emory Antibiotic Resistance Center
Gold Star Wives of America	HIV Medicine Association
Korean War Veterans of America	Immune Deficiency Foundation
Military Order of Foreign Wars	Infectious Diseases Society of America
Military Order of the Purple Heart	Making-A-Difference in Infectious Diseases
National Association for Uniformed Services	March of Dimes
National Defense Committee Reserve Officers Association	Musculoskeletal Infection Society
National Military and Veterans Alliance	National Association of County and City Health Officials
Society of Military Widows	National Association of Pediatric Nurse Practitioners
The Flag and General Officers Network	National Athletic Trainers' Association
The Retired Enlisted Association	ONCORD, Inc.
Tragedy Assistance Program for Survivors	Pediatric Infectious Diseases Society
Vietnam Veterans Association	Research!America
Alliance for Aging Research	Society for Healthcare Epidemiology of America
Alliance for the Prudent Use of Antibiotics	Society of Critical Care Medicine
American Academy of Allergy, Asthma & Immunology	Society of Infectious Diseases Pharmacists
American Academy of Pediatrics	Spero Therapeutics
American Association of Bovine Practitioners	TB Alliance
American Association of Swine Veterinarians	The American Association of Immunologists
American Gastroenterological Association	The Fecal Transplant Foundation
American Public Health Association	The Pew Charitable Trusts
American Society for Microbiology	Theravance Biopharma
American Society of Transplant Surgeons	Trust for America's Health
American Thoracic Society	UPMC Center for Health Security