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
If you have any questions or would like more information, please contact Rohini Kosoglu (Sen. Bennet) at Rohini_Kosoglu@bennet.senate.gov or Matthew Richardson (Sen. Hatch) at Matthew_Richardson@hatch.senate.gov.
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
American Military Retirees Association
American Military Society
American Retirees Association
Army Navy Union
Association of the United States Navy
Gold Star Wives of America
Korean War Veterans of America
Military Order of Foreign Wars
Military Order of the Purple Heart
National Association for Uniformed Services
National Defense Committee Reserve Officers Association
National Military and Veterans Alliance
Society of Military Widows
The Flag and General Officers Network
The Retired Enlisted Association
Tragedy Assistance Program for Survivors
Vietnam Veterans Association
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 Association of Swine Veterinarians
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
Emory Antibiotic Resistance Center
HIV Medicine Association
Immune Deficiency Foundation
Infectious Diseases Society of America
Making-A-Difference in Infectious Diseases
March of Dimes
Musculoskeletal Infection Society
National Association of County and City Health Officials
National Association of Pediatric Nurse Practitioners
National Athletic Trainers’ Association
ONCORD, Inc.
Pediatric Infectious Diseases Society
Research!America
Society for Healthcare Epidemiology of America
Society of Critical Care Medicine
Society of Infectious Diseases Pharmacists
Spero Therapeutics
TB Alliance
The American Association of Immunologists
The Fecal Transplant Foundation
The Pew Charitable Trusts
Theravance Biopharma
Trust for America’s Health
UPMC Center for Health Security