



Rear Admiral [Ret.] James J. Carey

National Chairman

6022 Knights Ridge Way, Alexandria, VA 22310-1635

PH: 703-971-3220 / Direct E-Mail: RADMCarey@aol.com

11 FEB 2016

Dear Chairman Alexander and Ranking Member Murray,

On behalf of THE FLAG & GENERAL OFFICERS' NETWORK, Inc., an official 501.c.19 War Veterans Organization representing 90 percent of all living U.S. Armed Forces Flag & General Officers (Guard, Reserve and Retired), I am writing to ask you to include S. 185, the bi-partisan Promise for Antibiotics and Therapeutics for Health (PATH) Act in your innovations' markup sessions. We are a signator of and totally in support of the attached letter sent to you by the National Military & Veterans Alliance [NMVA]: www.NMVA.us

PATH is so crucial because drug-resistant bacteria are infecting our military, veterans and fellow citizens at an alarming rate and, in far too many cases, we do not have the drugs to treat them. The Centers for Disease Control and Prevention (CDC) estimates that 2,000,000 infections with antibiotic-resistant bacteria occur each year in the United States and 23,000 Americans, including a significant number of wounded military veterans, die as a result.

PATH, by creating an approval pathway for limited population antibacterial drugs (LPAD), will take us one step further in developing antibiotics to treat serious, life-threatening infections for patients who have run out of options. Because these antibiotic-resistant infections are rare, it is difficult for drug developers to identify and enroll enough patients to perform the traditional, expensive, large-scale clinical trials. By allowing the Food and Drug Administration (FDA) to rely on smaller datasets than it does for other drugs, the pathway will reduce the large clinical trial costs and, likely, give patients faster access to life-saving treatments.

Drugs approved under the pathway would have to meet the same safety and efficacy standards as any other drug under existing law. Additional safeguards are in place: The drug's label will include a special designation from FDA indicating that the drug is intended for use only in a limited, high-risk population and the Department of Health and Human Services (HHS) will monitor how these approved antibiotics are being prescribed. It's important to note that these antibiotics will be used to treat extremely sick patients with few or no available treatment options, so their acceptable risk will be greater than those with access to effective treatments.

A similar provision overwhelmingly passed the House last year as part of the 21st Century Cures legislation, so now is the time to capitalize on this momentum by demonstrating Senate support for the companion bill. You demonstrated your leadership on this important issue when you championed the GAIN act in 2012. GAIN has helped to regenerate investment in antibiotic development and has brought us closer to delivering new, life-saving medicines to the growing number of Americans who urgently need them.

I ask that you continue your leadership role protecting the health of our service members and citizens. We urge you to include this legislation in your innovation agenda given its significant impact on our wounded military men and women, our aging veterans and grandparents, and our vulnerable children who are dying of superbug infections with no hope of treatment. Please know you have our continued thanks for your efforts on behalf of America's veterans and their families.

Signed

Rear Admiral [Ret.] James J. Carey, National Chairman

Rear Admiral [Ret.] James J. Carey, National Chairman
THE FLAG & GENERAL OFFICERS' NETWORK
www.FlagAndGeneralOfficersNetwork.org



An Official 501.c.19 War Veterans Organization!!!
Over 3800 U.S. Armed Forces Flag & General Officers
In Continued Service To America!!!