

THE FLAG & GENERAL OFFICERS NETWORK

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

www.FlagAndGeneralOfficersNetwork.org

30 January 2015

Senator Orrin Hatch

104 Hart Senate Office Building

Washington, DC 20510

Senator Michael Bennet

458 Russell Senate Office Building

Washington, DC 20510

Dear Senator Hatch and Senator Bennet,

THE FLAG & GENERAL OFFICERS' NETWORK, Inc., an official 501.c.19 war veterans' organization of three-fourths of all living U. S. Armed Forces Flag & General Officers [Guard, Reserve and Retired], now writes to you in strong support of the Promise for Antibiotics and Therapeutics for Health (PATH) Act. American active duty military personnel and veterans are dying from bacterial infections that existing antibiotics cannot treat. These brave men and women need new drugs to treat these diseases and save their lives. We strongly salute your efforts to address the problem of the dwindling antibiotic pipeline by establishing a regulatory approval pathway that will facilitate the development of these important new drugs to treat serious and life-threatening infections for which there are few or no other options.

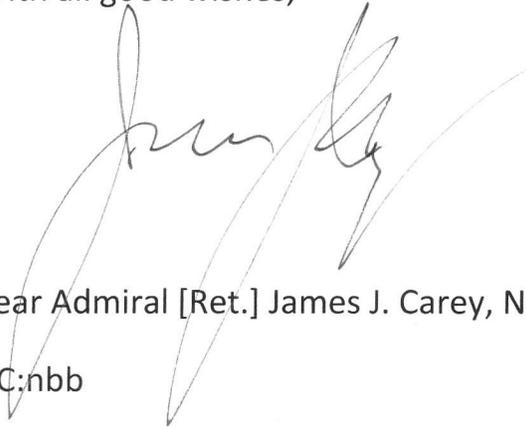
The current-day alarming rise in antibiotic resistance urgently requires a new, multi-pronged approach, including streamlining regulatory requirements in order to allow the U.S. Food and Drug Administration (FDA) to approve new antibiotics for patients with unmet needs. These patients include not only military personnel and veterans, but also their families—children, parents, and grandparents.

The PATH Act will authorize FDA to weigh the risks and benefits of a qualifying antibiotic in a targeted population of patients with serious infection and no other options. Ensuring FDA has the authority to make this risk/benefit calculation for this narrow population of patients could facilitate the development of these important therapeutics by allowing the agency to rely on smaller datasets than it does for antibiotics to treat broader groups of patients, some of whom may have other treatment options. The legislation includes important patient protections, including strong labeling requirements so that clinicians understand that these drugs have been approved under this new pathway and are intended specifically for those patients without other options. The legislation also requires that the U.S. Department of Health and Human Services monitor how this pathway is being used in order to ensure that these drugs are being prescribed to the patients who actually need them.

As I wrote in my commentary in *Roll Call* (enclosed), the fact that American soldiers and sailors are being saved from their combat wounds only to become the victims of these new untreatable superbugs requires immediate action to protect these men and women and their families from potentially fatal illnesses. The PATH Act is an important step toward addressing this pressing public health and patient safety problem.

We salute your efforts and leadership in recognizing that the threats that face our service men and women and our military war veterans in the form of untreatable infections. We stand ready to help you and your colleagues to ensure the speedy passage of this important legislation.

With all good wishes,

A handwritten signature in black ink, appearing to read "James J. Carey". The signature is fluid and cursive, with a large initial "J" and a long, sweeping underline that extends to the right.

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

JJC:nbb

Encl: *Roll Call* – Congressional Action in the Fight Against Superbugs

ROLL CALL

Congressional Action in the Fight Against Superbugs | Commentary

By James J. Carey

Jan. 16, 2015, 5 a.m.

If the members of the new Congress are looking for ways to show the world they can take action and get things done, I have a suggestion. How about a bipartisan piece of legislation that has the potential to help save injured troops and strengthen public health in the United States and across the globe?

Today, two senators, [Orrin G. Hatch](#), R-Utah, and [Michael Bennet](#), D-Colo., introduced a bipartisan bill to encourage the development of badly-needed antibiotics. It's similar in intent to a bipartisan bill introduced during the last congressional session in the House of Representatives.

The legislation addresses the looming crisis of antibiotic resistance, the rise of so-called "superbugs" that do not respond to any antibiotic treatment available today. Establishing a new pathway for antibiotic development has broad support among industry, public health groups, medical societies and veterans' organizations. Clearly the concept has bipartisan support on Capitol Hill, a fact that gives me real hope this Congress will take meaningful action.

The stakes couldn't be higher. Superbug infections are a global threat that costs thousands of lives every year — an estimated 23,000 in the United States alone. And according to a recent report from an advisory committee convened by the British Prime Minister, David Cameron, superbugs — including bacteria resistant to antibiotics — will cause 10 million deaths a year and as much as \$100 trillion in societal costs globally by 2050 if we do not act.

As a veteran, I know that antibiotic resistance poses a particular risk to our troops. Too many brave men and women have survived major combat injuries, only to succumb to infections that no approved antibiotic can treat. I think of Marine Lance Cpl. Jonathan Gadsden. After a roadside bomb exploded under his Humvee in Iraq, he survived airlifts to military hospitals in Baghdad and Germany, and to the National Naval Medical Center in Maryland. He died at age 20, not from his injuries, but rather from the multidrug-resistant infections that followed.

Tragically for soldiers such as Gadsden, we're falling behind in the race to find new antibiotics to combat superbugs. As bacteria continually adapt to defeat the drugs we have today, the pace of new drug development has slowed dramatically. In the 1980s, 29 new antibiotics were approved. In the 1990s, 23 were approved. In the 2000s, just nine made it to market.

The legislation introduced today would help overcome some of the regulatory hurdles facing new antibiotic development, and create a pathway to approve new antibiotics for patients who have no options left. The president has also recognized the threat of antibiotic resistance. In September, he

issued a national strategy that emphasizes the importance of using our existing antibiotics wisely, and the pressing need for new drug development.

The time is right. There is broad support for updating the antibiotics approval process from industry and the nonprofit sector. There is bipartisan support on both sides of the Hill and at the White House. For the sake of our returning troops and the millions of people worldwide at risk of untreatable infections, I hope this legislation is among the first bills to pass the new Congress.

Rear Admiral James J. Carey is the national chairman of The Flag & General Officers' Network and is chairman of the Science in Service to Humanity Foundation in Washington, D.C.