

July 24, 2014

The Honorable Gene Green 2470 Rayburn House Office Building Washington, DC 20515

Dear Representative Green:

The American College of Preventive Medicine (ACPM) greatly appreciates your leadership in introducing H.R. 3742, the Antimicrobial Development to Advance Patient Treatment (ADAPT) Act, that would address the antibiotic resistance crisis. Your bill allows for new treatments to be developed through an accelerated pathway at the Food and Drug Administration (FDA), thereby expediting patient access to new antimicrobial medications to treat infections resistant to antibiotics in limited and specific populations.

Through support of policies within the house of medicine and other venues that aim to promote the judicial use of antibiotics in animals, ACPM has been a leader in working to reduce the rapid development of microbial antibiotic resistance. Infectious diseases that have antibiotic resistance pose a growing threat to our nation's public health. According to the Centers for Disease Control and Prevention (CDC), approximately 23,000 Americans will die this year due to antibiotic-resistant infections. A total of 9,945 tuberculosis cases (a rate of 3.2 cases per 100,000 persons) were reported in the United States in 2012, out of which 72 cases were multidrug -resistant.

A growing number of patients are suffering from and succumbing to antibiotic resistant infections that cannot be treated with existing drugs. The ADAPT Act would address a key regulatory barrier to antibiotic R&D and speed patient access to important antibacterial and antifungal medications to treat serious or life-threatening infections. ADAPT would establish a new limited population approval pathway under which medications could be approved based upon smaller, more rapid clinical trials. At the same time expedited review was underway, quality standards would not be compromised; this new pathway would maintain FDA's standards of evidence for safety and effectiveness for the indicated population.

ADAPT further prevents the development of antibiotic resistance by updating breakpoints for susceptibility and requiring detailed labeling that notes approved use only for specific populations. This accelerated pathway provides important incentives to support the R&D needed to develop new medications with limited use.

We thank you for recognizing and promoting the need for new antibacterial therapies to treat patients with serious or life-threatening infections who lack sufficient therapeutic options. We offer to you ACPM's strong endorsement of the ADAPT Act, and look forward to working with you and your staff to realize the successful enactment of this bill.

Sincerely,

Halley S. Faust, MD, MPH, FACPM

Halley S. Fano, and

President