

June 9, 2015

Dear Representative Shimkus and Representative Green,

As leading organizations working to improve, promote and protect the public's health, we are writing to thank you for your ongoing efforts to address the growing threat posed by antibiotic resistance and the dearth of new antibiotics. We specifically commend you for introducing the Antibiotic Development to Advance Patient Treatment (ADAPT) Act. This legislation will establish a much needed pathway to deliver antibiotics to patients that desperately need them. Without such a pathway, we fear that antibiotic research and development will continue to decline leaving a growing number of patients with untreatable, life-threatening infections.

Antibiotic resistance is a serious patient safety, public health, and national security concern. In September of 2013, the Centers for Disease Control and Prevention (CDC) issued a report which conservatively estimated that over two million people in the U.S. are sickened every year due to resistant infections, and approximately 23,000 die. The real numbers are likely far higher. CDC identified a four-pronged strategy to combat antibiotic resistance: prevention; surveillance; improved use of antibiotics; and development of new drugs and diagnostics. Last fall, the President's Council of Advisors on Science and Technology (PCAST) echoed the CDC findings in their [\*Report to the President on Combating Antibiotic Resistance\*](#). PCAST also specifically recommended the development of new regulatory pathways to evaluate urgently needed antibiotics. Your legislation is a critical step in the development of new antibiotics.

The ADAPT Act would establish a new regulatory pathway to approve antibiotics to treat serious or life-threatening infections for the limited populations of patients with unmet medical need based upon smaller clinical trials. It is often not feasible for these drugs to be developed using traditional, large studies due to the limited numbers of patients in whom these infections currently occur. We are pleased that any drug approved under this new pathway must still meet the Food and Drug Administration's (FDA) standards of evidence for safety and effectiveness for the approved population.

The ADAPT Act recognizes that in making approval decisions, the benefit-versus-risk calculation for patients who lack therapeutic options will be different than for patients with easily treatable infections, while providing safeguards to discourage use of the drugs in patients who could be adequately treated with existing antibiotics. First, it includes special labeling requirements to alert healthcare providers that these drugs have only been demonstrated to be safe and effective for the indicated population. Second, FDA will have the authority to review promotional materials to help guard against marketing beyond those patients for whom the drug is appropriate.

This bill also requires that Health and Human Services monitor the use of the antibiotics approved under the pathway and potential changes in drug resistance. Public availability of this data is critical to ensuring appropriate stewardship of limited population drugs and improving surveillance of trends in resistance.

The ADAPT Act also takes important steps to ensure that susceptibility test interpretive criteria (also known as "breakpoints") for antimicrobial drugs are regularly updated and made publicly

available. A breakpoint can help guide appropriate use of antimicrobial drugs by providing clinicians with information that helps to predict whether the drug will be effective in a patient infected with a specific pathogen. Given the ongoing development of drug resistance and newly emerging pathogens, it is critical that breakpoints be updated in a timely manner.

Thank you again for your leadership in tackling the problem of antibiotic resistance. We look forward to working with you and your colleagues to make this bill as strong as it can be to most benefit public health and patient safety.

Sincerely,

American Public Health Association  
Association of State and Territorial Health Officials  
National Association of County and City Health Officials  
Trust for America's Health