

February 26, 2014

The Honorable Phil Gingrey, MD
442 Cannon House Office Building
Washington, DC 20515

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

Dear Representatives Gingrey and Green:

The undersigned organizations represent healthcare providers, hospitals, pharmacists, clinical laboratory scientists and medical microbiologists, public health experts, patients and advocates. We write to thank you for introducing the Antibiotic Development to Advance Patient Treatment (ADAPT) Act. This critical legislation will establish a much needed limited population approval pathway to speed patient access to new antibacterial drugs that treat serious or life-threatening infections where an unmet medical need exists. Without such a pathway, we fear that the antibiotic research and development (R&D) will continue to struggle, and that patients will continue dying without new treatments.

Antibiotic resistance is a serious patient safety, public health, and national security concern. In September, the Centers for Disease Control and Prevention (CDC) issued a [report on antibiotic resistance threats](#) which conservatively estimated that over 2 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, as our current surveillance and data collection capabilities cannot capture the full burden. CDC specifically recommends the development of new antibiotics to address this public health crisis, and your legislation is a critical step in that effort.

In 2011, one superbug, carbapenem-resistant *Klebsiella pneumoniae*, spread through the National Institutes of Health's own Clinical Center, infecting 17 and killing 6 over a six month period of time. Extensively drug resistant *Klebsiella* bacteria kill up to 50% of infected patients despite treatment with last resort drugs, and resistance rates for these and other resistant bacteria continue to climb.

Everyone is in danger of contracting a serious infection due to superbugs, but certain populations are at heightened risk:

- Immune-compromised individuals, including the elderly, chemotherapy patients and transplant patients, are at heightened risk for contracting and dying from a serious drug-resistant infection.
- Children are more vulnerable to bacterial illnesses than adults, particularly preterm infants and other children with special healthcare needs. Pediatric treatment options are even more limited than those for adults.
- Women and men who have sex with men are particularly concerned about the rise of drug-resistant *Neisseria gonorrhoeae* (the pathogen that causes gonorrhea). For women, according to the CDC, this may lead to an increase in pelvic inflammatory disease and

infertility. For both populations, the increase in gonorrhea could lead to increases in new HIV infections as gonorrhea can facilitate the acquisition and transmission of HIV.

- Soldiers are uniquely vulnerable to superbugs entering the body through deep combat wounds or burns and leading to increased limb loss, sepsis and death. According to available data from the Department of Defense, approximately 3,300 service members that were treated in military treatment facilities during 2004-2009 were infected with one very lethal superbug, *Acinetobacter*.¹
- HIV patients and others with compromised immune systems are at heightened risk for drug-resistant tuberculosis (TB), which is on the rise globally. Curing resistant TB is extremely difficult and can cost more than 100 times as much as curing typical TB according to the World Health Organization (WHO)²; it also can take years, and some of the drugs cause side effects like deafness and psychosis.

The ADAPT Act will build on the success of the Generating Antibiotic Incentives Now (GAIN) Act by allowing antibacterial drugs to treat serious or life-threatening infections to be approved based upon smaller clinical trials. It is often not feasible for these drugs to be developed using traditional, large clinical trials due to the limited numbers of patients in whom these infections currently occur. Importantly, 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 limited indicated population.

Judicious use of drugs approved under this pathway is critical for optimal patient care and public health efforts to protect against the development of resistance. We appreciate ADAPT's provisions aimed at this goal, including the requirement that the labeling of drugs approved under this pathway state that they are approved for a limited population. We recommended strengthening this provision by requiring the label to include a prominently placed visual element, such as a logo, to clearly indicate to the healthcare community that these drugs are approved for a limited population and must be used prudently.

As medical, healthcare, public health and patient organizations dedicated to patient care and safety, as well as public health in general, we thank you for introducing the ADAPT Act. We look forward to working with you toward the establishment of a limited population approval pathway to speed patient access to new life-saving antibacterial drugs.

Sincerely,

AIDS Action Baltimore, Inc.
Alliance for Aging Research
American Academy of Otolaryngology-Head and Neck Surgery
American Academy of Pediatrics
American College of Preventive Medicine
American College of Rheumatology

¹ 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.

² Tuberculosis fact sheet. World Health Organization. <http://www.who.int/trade/glossary/story092/en/>

American College of Surgeons
American Medical Association
American Thoracic Society
Association for Professionals in Infection Control and Epidemiology
Center for a Livable Future
Coalition of State Rheumatology Organizations
Council of State and Territorial Epidemiologists
Dignity Health
Food Animal Concerns Trust
Harm Reduction Coalition
HIV Medicine Association
Infectious Diseases Society of America
National Association of County and City Health Officials
National Association of Pediatric Nurse Practitioners
National Coalition of STD Directors
National Foundation for Infectious Diseases
Pediatric Infectious Diseases Society
Society for Healthcare Epidemiology of America
Society of Critical Care Medicine
Society of Infectious Diseases Pharmacists
The Pew Charitable Trusts
Treatment Action Group
Trust for America's Health
UPMC Center for Health Security