

May 21, 2015

The Honorable Fred Upton  
Chairman  
Committee on Energy & Commerce  
U.S. House of Representatives  
2125 Rayburn House Office Building  
Washington, DC 20515

The Honorable Frank Pallone  
Ranking Member  
Committee on Energy & Commerce  
U.S. House of Representatives  
2125 Rayburn House Office Building  
Washington, DC 20515

Dear Chairman Upton and Ranking Member Pallone:

The undersigned organizations represent healthcare providers, hospitals, pharmacists, clinical laboratory scientists and medical microbiologists, public health experts, patients and advocates. **We write in strong support of Section 2121 of the 21<sup>st</sup> Century Cures legislation** (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*.<sup>1</sup>
- 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 drug-sensitive TB, according to the World Health Organization (WHO)<sup>2</sup>; it also can take years to cure and some of the drugs have side effects including 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.

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 including the ADAPT Act in the 21<sup>st</sup> Century Cures initiative. We urge the Committee to take this opportunity to work toward the establishment of a limited population approval pathway to speed patient access to new life-saving antibacterial drugs.

Sincerely,

Alliance for Aging Research  
 American Academy of Allergy, Asthma & Immunology  
 American Academy of Pediatrics  
 American College of Preventive Medicine  
 American College of Rheumatology  
 American College of Surgeons  
 American Gastroenterological Association  
 American Thoracic Society  
 Association for Professionals in Infection Control and Epidemiology  
 Dignity Health  
 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  
Trust for America's Health

CC:

The Honorable Joseph Pitts  
The Honorable Gene Green  
The Honorable Diana DeGette  
The Honorable John Shimkus