

September 17, 2015

The Honorable Charles Boustany
U.S. House of Representatives
1431 Longworth House Office Building
Washington, DC 20515

The Honorable Mike Thompson
U.S. House of Representatives
231 Cannon House Office Building
Washington, DC 20515

Dear Representatives Boustany and Thompson:

The undersigned organizations representing healthcare providers, hospitals, pharmacists, scientists and microbiologists, industry, public health experts, patients and advocates write to express our support for the Reinvigorating Antibiotic and Diagnostic Innovation (READI) Act of 2015.

We are deeply concerned about the alarming rise of antibiotic resistant infections and the insufficient number of new antibiotics and diagnostics to care for patients. More and more people are contracting serious and life-threatening infections that are difficult and sometimes impossible to treat, resulting in longer hospital stays, complications to other medical treatments such as surgery or chemotherapy, and even deaths. Patients with weakened immune systems, such as those with HIV/AIDS, preterm infants, cancer patients, transplant patients, the elderly, or patients treated in intensive care units are at heightened risk, but even healthy young people are contracting and dying from serious, antibiotic resistant infections.

The President's Council of Advisors on Science and Technology (PCAST), Centers for Disease Control and Prevention (CDC), World Health Organization (WHO) and other expert bodies and individuals have documented the urgent crisis of antibiotic resistance and called for a renewed investment in antibiotic and diagnostics research and development (R&D). Providing incentives for the development of new antibiotics and diagnostics is a key goal of the White House National Strategy for Combating Antibiotic Resistant Bacteria. Your legislation is an important component of this urgently needed effort.

Antibiotic development has dwindled, with many pharmaceutical companies leaving this market. Significant economic hurdles continue to hamper antibiotic R&D. Antibiotics are typically inexpensive, used for a short duration and held in reserve to protect their utility. Your legislation would build upon the success of the Generating Antibiotic Incentives Now (GAIN) Act, enacted in 2012, which provides an extra 5 years of exclusivity for a new antibiotic or antifungal drug that treats a serious or life-threatening infection. GAIN provides a "pull" incentive—which rewards a company after its drug is brought to market. Your bill would provide a "push" incentive—which assists a company during the costly and risky drug development process. Economic experts agree that a combination of push and pull incentives will be needed to effectively stimulate antibiotic R&D.

Equally important, we need new, rapid diagnostics to quickly identify the pathogen infecting a patient. This will allow faster, more appropriate treatment, improving patient outcomes,

shortening hospital stays, and reducing costs associated with unnecessary treatment. Diagnostics also have a significant impact on public health. Diagnostics are critical for guiding the appropriate use of antibiotics, which is essential for limiting the development of resistance and protecting patients from adverse events associated with inappropriate antibiotic use, such as deadly *Clostridium difficile* infections, which claim 29,000 lives annually according to the CDC. Diagnostics are also necessary for quick identification of outbreaks and activation of appropriate public health responses. Lastly, diagnostic tests are critical for identifying patients who are eligible for antibiotic clinical trials.

Unfortunately, diagnostics R&D faces significant challenges, including the high cost of collecting specimens needed to validate new tests, the significant cost of training laboratories to evaluate new tests, and inadequate reimbursement for tests once they reach the market. Your legislation would significantly help reduce this economic barrier and foster the development of needed new diagnostics.

We thank you for your leadership on these important issues and look forward to working with you to advance this legislation.

Sincerely,

AdvaMedDx

Accelerate Diagnostics, Inc.

Alere, Inc.

Alliance for the Prudent Use of Antibiotics

American Academy of Allergy, Asthma & Immunology

American Academy of Emergency Medicine

American Association of Bovine Practitioners

American College of Rheumatology

American Congress of Obstetricians and Gynecologists

American Gastroenterological Association

American Society for Microbiology

American Society of Health-System Pharmacists

American Thoracic Society

American Urological Association

Antibiotics Working Group (Cempra, Durata Therapeutics, Optimer Pharmaceuticals, Melinta, The Medicines Company and Theravance)

Association for Professionals in Infection Control and Epidemiology

BD

bioMérieux

Cempra, Inc.

Center for Foodborne Illness Research & Prevention

Da Volterra

HIV Medicine Association

Infectious Diseases Society of America

Making-A-Difference in Infectious Diseases

March of Dimes Foundation

Merck
Microbion Corporation
National Association of County & City Health Officials
National Association of Pediatric Nurse Practitioners
National Athletic Trainers' Association
National Foundation for Infectious Diseases
Pan American Society for Clinical Virology
Peggy Lillis Foundation
Pediatric Infectious Diseases Society
Renal Physicians Association
Research!America
Society for Healthcare Epidemiology of America
Society of Infectious Disease Pharmacists
Theravance Biopharma
UPMC Center for Health Security