CUBIST
PHARMACEUTICALS

December 13, 2013

The Honorable Phil Gingrey, M.D.
442 Cannon House Office Building
Washington, DC 20515

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

Dear Congressman Gingrey and Congressman Green,

I am writing to express the strong support of Cubist Pharmaceuticals for the Antibiotic Development to Advance Patient Treatment Act of 2013. The Act promises to accelerate innovation against the serious public health threat of antimicrobial resistant organisms, building upon the success of the Generating Antibiotic Incentives Now (GAIN) Act, which you also sponsored. We strongly encourage your colleagues to sponsor the ADAPT Act and to support its enactment into law at the earliest opportunity.

Cubist is a biopharmaceutical company focused on the research, development and commercialization of pharmaceutical products especially antibiotics that address critical needs in the acute care environment. Headquartered in Lexington, Massachusetts, we currently market CUBICIN® (daptomycin for injection), the first intravenous (IV) antibiotic from a class of anti-infectives called lipopeptides. In the wake of a highly successful launch of CUBICIN, the company has a growing pipeline that includes antibiotic candidates for difficult to treat infections including Clostridium difficile and serious Gram-negative infections, including those caused by multi-drug resistant Pseudomonas aeruginosa. Since enactment of the GAIN Act, Cubist has received Qualified Infectious Disease Product (QIDP) designations as well as Fast Track status for its investigational antibiotics ceftolozane/tazobactam, tedizolid phosphate (TR-701), and surotomycin.

The Antibiotic Development to Advance Patient Treatment Act would ensure that the breakpoints (also known as *susceptibility test interpretive criteria*) of QIDPs are based upon the totality of best available evidence; strengthen our national surveillance against resistant infections; and ensure that the breakpoints of older antibiotics are up-to-date.

The Act also creates an expedited approval pathway for new antibiotics for use in limited patient populations. Cubist is committed to helping ensure that patients have timely access to safe and effective new medicines, and we recognize that antibiotic-resistant infections represent an urgent and unique public health challenge. The creation of an expedited development and approval pathway under section 505 of the Federal Food, Drug, and Cosmetic Act specific to antimicrobials must not place direct or indirect restrictions on the practice of medicine, including the ability of physicians to attend to patient needs in a timely manner using all available treatment options.

We also hope that FDA, CDER, and the relevant new drug reviewers exercise their existing regulatory authority now to expedite access of innovative antibiotic treatments to patients.

Sincerely,

12/13

Mark Battaglini
Vice President, Government Affairs
Cubist Pharmaceuticals