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**Subject: FDA Prescription Drug User Fee Act (PDUFA) reauthorization legislation,  
New product approval mechanism for antimicrobials (LPAD)**

Dear Sirs,

Basilea Pharmaceutica International Ltd., one of few companies worldwide still committed to R&D for new antimicrobials to combat resistant life-threatening infection, strongly urges Congress to establish a new antimicrobial drug approval pathway as part of the upcoming Prescription Drug User Fee Act (PDUFA) legislation. We support the concept of a new limited regulatory approval mechanism intended specifically for drugs that are useful in the treatment of serious microbial infections where very few therapeutic options currently exist.

The Infectious Disease Society of America (IDSA) has, in consultation with FDA experts, proposed a new product approval mechanism currently referred to as "LPAD" "Limited Population Antibacterial Drug". This mechanism will provide a vital lifeline to patients across America faced with severely drug-resistant infections due to bacteria and fungi. In addition, this new proposed pathway provides a potential avenue for more efficient antimicrobial drug development for certain much needed drugs for resistant infections than is possible under current legislation.

Under the proposed LPAD mechanism, a novel antibacterial or antifungal drug's safety and effectiveness would be studied in substantially smaller, more rapid, and less expensive clinical trials. Consistent with existing drug approval standards, LPAD drug sponsors will need to demonstrate to the Food and Drug Administration's (FDA) satisfaction that LPAD products are safe and effective for their intended use and that the drugs' benefits outweigh their risks for the indicated populations. LPAD products then would be narrowly indicated for use in small, well-defined populations of patients for whom the drugs' benefits have been shown to outweigh their risks.

Large Pharmaceutical companies have largely left antimicrobial development not only because of the challenges of market returns, but also because the existing pathways for the

development and approval of new antimicrobials are arduous, risky, and, for some highly-resistant infections, infeasible. Moreover, these pathways are inherently flawed in that they encourage companies to develop and commercialize therapies that target the broadest possible populations and maximize use. This is precisely the wrong strategy in the interests of antimicrobial stewardship and minimizing the development and spread of resistance.

Smaller companies such as Basilea Pharmaceutica International Ltd. are committed to undertake R&D to fight serious drug resistant infections. The proposed LPAD pathway provides a much needed pathway to the more efficient development of critically needed life-saving antimicrobial drugs and also reinforces their responsible use.

In addition to the specific proposal of the Infectious Diseases Society of America (IDSA) which limits itself to antibiotics for bacterial infections we wish to highlight the even greater lack of new antifungal drugs for patients with serious life-threatening fungal infections. We are therefore highly encouraged to see that the draft proposed legislation has already provision for anti-fungals as "qualified infectious disease products" [page 6, 19 (g)]. Indeed, with logic and foresight, the FDA has already combined the regulatory expertise required for evaluation of both anti-bacterial and anti-fungal products into the same division.

Consequently, we recommend that the mechanism proposed by the IDSA as "LPAD" and under consideration in the draft legislation be supported by Congress. However, we also recommend that this mechanism be renamed to more precisely reflect the intent and wording of the proposed Bill by replacing term "Antibacterial" with "Antimicrobial" so that LPAD will stand for "Limited Population Antimicrobial Drug" .

If Congress fails to support this new mechanism and other incentives, the few remaining companies undertaking R&D in this area will face increasing pressures to abandon their research efforts and no new antimicrobial drugs will be available to treat patients with the rising tide of multi-drug resistant life-threatening infections.

Sincerely,



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cc.  
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