April 12, 2012

The Honorable Fred Upton
Chairman, House Committee on Energy and Commerce
2183 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Henry Waxman
Ranking Member, House Committee on Energy and Commerce
2204 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Joe Pitts
Chairman, Subcommittee on Health, House Energy and Commerce Committee
420 Cannon House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Ranking Member, Subcommittee on Health, House Energy and Commerce Committee
237 Cannon House Office Building
Washington, DC 20515

Dear Representatives Upton, Waxman, Pitts, and Pallone:

We, the undersigned pharmaceutical companies, strongly urge Congress to establish a new antibacterial drug approval pathway as part of the upcoming Prescription Drug User Fee Act (PDUFA) legislation. The concept we support, put forward by the Infectious Diseases Society of America (IDSA), is a Limited Population Antibacterial Drug (LPAD) approval mechanism intended specifically for drugs that are effective in the treatment of serious bacterial infections where very few therapeutic options currently exist. This mechanism will provide a vital lifeline to patients across America faced with severely drug-resistant infections. In addition, this new proposed pathway provides an avenue for more efficient antibacterial drug development, and a more responsible regulatory pathway than available under current law. In this way, the LPAD product approval mechanism is a necessary complement to the economic incentives for antibacterial development that Congress currently is considering for inclusion in PDUFA.

Our companies, collectively representing hundreds of scientists, clinicians, and other employees, have been drawn to work in the antibacterial space because of the growing and severe threat to patients of drug resistance, and the potential to develop new drugs that meet this unmet medical need and bring a return to our investors. What we have found is that many pharmaceutical companies have abandoned antibacterial development not only because of the challenges of market returns, but also because the current regulatory pathways for the development and approval of new antibacterials 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 maximum use. This is precisely the wrong strategy in the interests of antibacterial stewardship and minimizing the development and spread of resistance. The LPAD pathway provides a much needed avenue towards more efficient development of certain critically needed antibacterial drugs that will provide these life-saving medicines to patients where the risk/benefit is balanced while simultaneously promoting their responsible use.

Under the LPAD mechanism, a novel drug's safety and effectiveness would be studied in smaller, more rapid, and less expensive clinical trials—much like the Orphan Drug (OD) Program permits for other rare diseases. Consistent with existing drug approval standards,

LPAD drug sponsors will need to demonstrate to the Food and Drug Administration (FDA) 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 approved for use in the indicated small and defined populations of patients. For patients with serious infections and insufficient therapeutic options, a greater degree of uncertainty about overall risk associated with a drug can be tolerated. Later, as more safety and efficacy data are generated in additional clinical trials, the potential to address new infection types or to expand the indicated population could occur through this or more traditional pathways.

Our companies recognize that this pathway implies a limited population, added restrictions, as well as the duty to conduct further monitoring and studies in safety and efficacy, as may be required through existing law. However, we believe that the LPAD approval pathway provides an opportunity for our products to reach patients in need efficiently and with sufficient return.

If Congress fails to act, there is a real possibility that the combined disincentives of market failure and regulatory challenges will not be overcome even if incentives currently under consideration in PDUFA are enacted. Our companies will face increasing pressures to abandon antibacterial drug development science, losing the experience and capabilities of our employees, and failing the clear needs of physicians and patients who face a growing threat.

For further information on the LPAD mechanism, please review the IDSA comments on the LPAD concept, including draft legislative language and other background materials submitted to your Committee earlier today.. Should you have any questions, please feel free to contact us. Contact information for our companies can be found enclosed.

Sincerely,

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Achaogen, Inc.

Gregory T. Went /s/ DE

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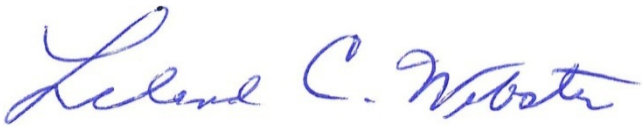

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Enclosure: Signatory Companies' Contact Information

Cc: Representative Phil Gingrey

Representative Gene Green

Enclosure

Limited Population Antibacterial Drug (LPAD) Approval Mechanism Support Letter

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