STIMULATING THE ANTIMICROBIAL PIPELINE:
A POLICY ANALYSIS OF THE GENERATING ANTIBIOTIC INCENTIVES NOW ACT AND OTHER POLICY ALTERNATIVES

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Antimicrobial-resistant infections affect at least 2 million Americans each year, with $20 billion in direct health care costs. This growing concern regarding antimicrobial resistance has made national headlines in media outlets and research journals. Current policy measures like the Generating Antibiotic Incentives Now (GAIN) Act are failing to address the problem. The Obama administration enacted an executive order in September 2014 to address the public health issue at hand. Speedy drug approvals and reimbursement models are policy recommendations that could spur the development of new effective antimicrobials and preservation of current antimicrobials, playing a pivotal role in this pressing matter.

The antimicrobial drug pipeline is drying up, and there is a pressing need to develop novel antimicrobial drugs. To address the lack of antimicrobials in development, Congress enacted the Generating Antibiotic Incentives Now (GAIN) Act of 2011. The provisions of the GAIN Act include market exclusivities, priority review and fast-track approval to encourage and incentivize companies to develop new antimicrobials.

This policy analysis examines and evaluates the GAIN Act based on a set of determined criteria: effectiveness, cost-benefit and political feasibility. As a pull mechanism that rewards the research output, the GAIN Act is a step in the right direction in terms of implementing strategies to combat the antimicrobial pipeline issue. However, it may not be enough. The issue at hand is a complex combination of scientific, regulatory, and economic facets. Therefore, it will be useful to consider other strategies to complement the GAIN Act and help address the other bottlenecks and gaps in the pipeline. In particular, the strategies will focus on the later stages of product development similar to the market exclusivities and other provisions of the GAIN Act. This analysis considers the advantages and disadvantages of three policy alternatives in the context of the GAIN Act. Based on the determined criteria, an approval mechanism used for urgent, unmet medical needs and the pay-for-treatment reimbursement model are the most promising alternatives.