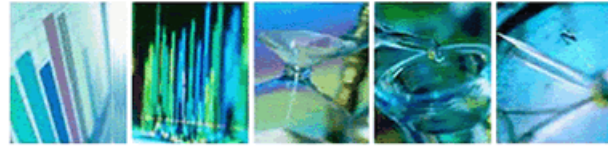




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Strategic Solutions for Managed Markets

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The Value of the P&T Committee in a Changing Market

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Health plan P&T committees serve as the internal committees empowered to evaluate and determine access to pharmaceutical products. While managed care does not drive specific therapies used by physicians, they do provide preferred formulary positions to those seen as more valuable. Should therapies be perceived as equally efficacious and safe, then appropriate financial analysis will determine therapeutic preferences. It is important for manufacturers to keep in mind that health plans generally review each product, or class of products, in all disease states, at least once a year -- regardless of product life cycle. The rigor of these reviews has already increased in the face of several product withdrawals and additional safety scrutiny on the part of the FDA, and we expect this trend to continue with the advent of comparative effectiveness research.

Considering these dynamics, it is important for manufacturers to understand the influence these committees may have on their product. The Zitter Group is in a unique position to provide insights into this exact issue because of the P&T Perspective. P&T Perspective is a realistic simulation of an actual health plan P&T committee meeting. It takes into account committee composition, meeting length, member preparation, and objectivity due to its double-blinded format. Additionally, all members of the P&T Perspective committee currently sit on P&T committees for active health plans.

The following are take-aways from a recent P&T Perspective review:

A manufacturer's successful launch of a new therapy or an existing branded agent touting new indications can be difficult when the category has significant generic penetration. In a recent review, the majority of products within the category were either generically available or would be in the next two years. This type of class is one of the most challenging in which to market branded agents due to two key challenges – generic penetration and limited data showing superiority of one agent over the others.

Managed care is unlikely to provide access to a new therapy having little empirical data unless it is clearly differentiated from current therapies in the eyes of the P&T committee. That being said, marketers of branded agents in any class with significant generic penetration may consider the following to increase the potential for a favorable review by the P&T committee:

- *Provide data to support differentiation of the new product versus incumbents: head-to-head studies, outcomes showing down-the-line cost savings, and/or other differentiators such as compliance data comparisons. Include these data in the AMCP dossier which is used by the P&T committee when evaluating new therapies*
- *Contract and rebate aggressively to counter generic competition particularly when there is no evidence of superior efficacy*
- *Focus marketing efforts on product attributes where evidence differentiates the product from generic competitors*

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