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## Reprint

### CONTROLLING YOUR BRAND'S SWITCH DESTINY

By Jack Pfister

A shifting, global regulatory environment, complex consumer behavior, and unpredictable competitive response all contribute to the complexity of the Rx to OTC switch decision.

An effective strategy for maximizing the profitability of a switch begins prior to even Rx approval. The optimal timing of the actual switch may not always coincide with the end of patent protection, bottoming Rx sales, or loss of competitive advantage. Multivariate models are now available to help pharmaceutical marketers develop more preemptive strategies for switching.

#### New FDA Emphasis on Economics

The consensus among attendees at the Institute for International Research's recent RX to OTC Switch Marketers Forum—held November 19-21, 2003, in Philadelphia, PA—was that FDA Commissioner Mark McClellan is bringing a new emphasis on societal economics to the FDA, which has pharmaceutical marketers rethinking their OTC switch strategies. According to Senior Associate Commissioner Jeff Weber, as reported in the February 10, 2003 edition of the Tan Sheet, McClellan has targeted the FDA's budgeting goals to anticipate an average increase of 50% for Rx-to-OTC switches.

"This puts us in a more proactive switch environment," according to Susan Lavine Coleman, president of Lawrenceville, NJ based NCI Consulting, which has evaluated more than

200 domestic and international OTC switch candidates. "More than his predecessors, McClellan sees switching as a way of increasing access and taking some of the drug costs out of the healthcare system," according to Coleman. She made her remarks in a presentation entitled, "Controlling Your Brand's Switch Destiny."

Managed care organizations agree.

#### Choices for Managed Care Members

With rare exceptions, managed care organizations no longer cover medicines once they achieve OTC status, and providers scrutinize utilization of the specific drug and its entire class. Even if only one member of the class switches, the entire class may be elevated into higher, non-formulary copay levels. Providers increasingly are offering coupons and other switch incentives, often with the financial backing of the new OTC's manufacturer, to encourage switching to the OTC product.

MCO members are faced with the economic decision of continuing with their present drug at a higher out-of-pocket expense, switching to the OTC, or even leaving the class for a lower-priced, older OTC. "If you were using a PPI other than Prilosec®, you might decide that Pepcid® and Tums® are an acceptable, cheaper alternative," Coleman says.

Does this mean the FDA will act on petitions, from private providers, to force OTC switching?

"In recent months, the FDA has backed away from what looked like a threat of forced switching," says



"What we are seeing with non-sedating antihistamines, and proton pump inhibitors is just the beginning," says NCI Consulting's Susan Lavine

Coleman, citing their apparently waning interest in Wellpoint's petition to mandate OTC status for non-sedating antihistamines. However, Coleman expects competitive forces and other interested constituencies to continue reopening the issue. "Even if FDA ultimately pursues forced switches, any mandate is bound to be met with extensive litigation," says Coleman.

### Europe Proactive on Switching

Not surprisingly, most of the buzz during Philadelphia's Rx-to-OTC conference was centered on the breaking news of the possibility of OTC statins in the UK as early as next year. Like McClellan, the UK Health Ministry also sees switching as a way to move drug costs out of the healthcare system. This could encourage other European countries to switch chronic therapies to over-the-counter, with or without manufacturer cooperation.

### When to Initiate a Product's OTC Strategy

"The assessment should begin in Phase II, allowing time for Phase III protocols to be modified, if appropriate, to incorporate OTC doses and endpoints," said Coleman.

During that assessment, marketers may decide not to pursue any additional studies and keep Phase III trials as simple as possible. The tradeoff for accelerating approval is incurring higher costs later, closer to the actual switch.

"Either way," says Coleman, "companies that take a hard look at the long-range life cycle of the molecule, Rx and OTC, and might find additional opportunities and threats for the drug that is not apparent in the Rx-only analysis."

Marketers customarily perceive switching prior to patent expiration as risky. MDs may discontinue prescribing the drug, patients may feel its value is diluted by its widespread availability, MCOs may drop it from formularies and cannibalization may have been underestimated.

"But marketers should be aware that, in this evolving environment, they may lose control of their brand's lifecycle due to payer, competitive or regulatory initiatives. It will take flexible thinking and proactive planning to maintain control," says Coleman.

### Switch Strategy Modeling

Multivariate models, such as NCI Consulting's Switch Evaluation System are tools that can help marketers compare the timing requirements and financial merits of various switch strategies.

Developed specifically for the pharmaceutical market, these models are designed to be continuously updated with input from highly specific market research to reflect the latest market conditions and competitive behavior. A well-engineered model allows manipulation of these inputs to test alternative assumptions without corrupting the integrity of the model.

"They are not black boxes that inscrutably provide 'the' answer," Coleman says. "They allow marketers to isolate individual decision points from the complexity, clutter and distraction caused by the interaction of multiple market factors." By factoring in all of those interactions, the model ensures none are overlooked, yet allows the marketer to test the sensitivity of individual variables.

For example, let's say that an MCO supported an OTC switch with an intensive three month coupon campaign, then abruptly stopped. There are a lot of interrelated consequences, some subtle, some far in the future. Multivariate models allow marketers to test responses to this scenario before committing to them. That way, they don't have to do something entirely intuitive, which can be bad, or nothing at all, which is worse.

### Brand Management Cooperation

Their objectivity means the models can also serve as arbitrators to foster Rx and OTC brand management cooperation.

The FDA's increased sense of consumer activism and Europe's proactive switch environment may obsolete the old, "switch at the end of patent" strategy. Patent expiration has traditionally been the handoff point for P&L responsibility from the Rx to the OTC brand managers. A cooperative strategy allows the development of a life cycle plan that covers both sides of the counter, enabling preemptive switching, brand divestiture, or dual Rx and OTC status if market conditions demand.

For companies without OTC divisions, a proactive, cooperative strategy simplifies the identification and development of switch partnerships.

"Developments are unfolding on an unprecedented, global scale," Coleman says. "We need to be prepared and equipped to, as Hubertus Cranz, Director-General of the Association of the European Self-Medication Industry says, 'expect the unimaginable.'"

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