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STRATEGIES FOR OVERCOMING THE INTERNAL CHALLENGES BETWEEN RX AND OTC

By **Jack Pfister**

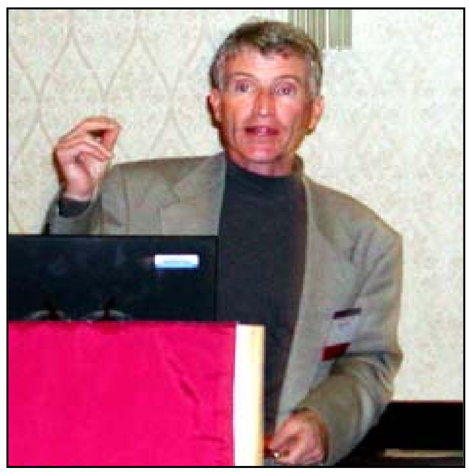
Why is the decision to switch from Rx to OTC usually considered a challenge? Is it because Rx and OTC marketing are seen as two separate sectors of a drug's product life cycle, with OTC always serving as the final stage? Or is it the stigma of lower profitability, deserved or not, that OTC-only marketing carries? These perceptions – or misconceptions – may sometimes cause a company's general management to be reluctant to concede to switching until the optimal timing for maximizing the contribution of a brand has passed.

In fact, OTC is a strategic option for extending a product's revenue stream and is not automatically the death knell to the prescription business. If Rx and OTC marketers construct a master life cycle strategy together, they can turn the paradigm of switching from a risk to an opportunity.

That was the message delivered by Bruce Lifka, Senior Director, Hair Growth and Rx/OTC Switches for Pfizer, at The Institute for International Research's *RX to OTC Switch Marketers Forum* held in Philadelphia in November, 2003.

Switching Need Not Be a Zero-sum Game

As Lifka put it, "Rx brand managers ask, 'why should we compromise a corporate asset like a billion dollar prescription franchise by converting it to an OTC with a net present value of 50 million dollars?' First of all," he answers, "almost every product's unit potential is higher in OTC than in prescription. You should be thinking of a drug's untapped OTC potential as an underutilized corporate asset, and manage the molecule to capitalize on both marketing channels. It does not have to be a zero-sum game."



"Rx marketers have always associated 'switch' as a threat; we need to speak in terms of a life cycle 'extension'." Bruce Lifka, Senior Director, Hair Growth and Rx/OTC Switches for Pfizer

Lifka feels switching is an effective strategic tool for category expansion, particularly for disease states that are sometimes "quasi-chronic," addressing the needs of patients who prefer to partially manage their own treatment.

In a broad sense, there are three categories of consumers, according to Lifka. "The percentages will vary by disease, but one kind of consumer will always choose to use prescription drugs, the second type will only use OTCs and the third migrates back and forth between Rx and OTC," he said. "Most individuals," claimed Lifka, "do not want to be on a chronic medication. Some consider being under a physician's care as a distressing sign of being more seriously ill."

Lifka cited arthritis as an example. Patients in this category might use the prescription strength for a few months until their condition stabilizes, then revert to the OTC to treat occasional flare-ups. A category expansion OTC strategy, therefore, would not erode patient office visits, but would satisfy consumer preferences and maximize the drug's use for the entire disease state.

Switching as a Brand-building Tool

In some instances, OTC versions should be launched prior to patent expiration, with separate Rx and OTC indications and dosing, supported by synergistic professional and consumer marketing. That way, switching becomes an effective strategic tool for brand building.

In some markets, consumer empowerment is changing the global economic and sociological environment, forcing pharmaceutical companies to switch earlier. In others, new classes threaten to make existing franchises obsolete. In either scenario, brand building is also a strong, strategic option.

"Brand building is my favorite switch scenario," said Lifka. He cited Robitussin® as an example when OTC marketing reinforced existing professional support through the broader, consumer-oriented channels. "During the mid to late 80's, Robitussin® migrated from being only sold in pharmacies to a mass-marketed product being advertised on television. We had already built a strong support base among physicians and pharmacists with the Rx, codeine formulations. We found physicians' recommendation rates for the OTC products increased with the mass-marketing campaign. We realized that doctors and pharmacists are also consumers who watch television."

Lifka recalled the case of the H2 antagonists as another example. "Even though their market was still growing 16% annually, the impending approval of proton pump inhibitors was barreling down on them," he said. Pepcid® got a jump on the competition by switching first and outspending them three to one. They went after the acid reducer market for the OTC while maintaining the GERD indication in the professional business. When the response generated by the OTC launch expanded the entire category's volume, they maximized the revenue stream by being entrenched in both the consumer and professional markets. "By the time Tagament® was switched," noted Lifka, "it was off patent, and the brand had already lost professional support and loyalty to other H2 formulations."

Lifka cites another example where a brand building strategy developed synergies between practice-based and consumer markets. Both Advil® and Aleve® detailed the professional market and established their new, OTC identities of the prescription legacies, Motrin® and Naprosyn®. Nuprin® underestimated the need for physician support prior to OTC launch and, subsequently, has always claimed a smaller market share in ibuprofen. Like Tagament, Orudis® did not switch until after they had lost their patent and their brand-based, professional market share and support.

> ***"The OTC extension vision should apply across an entire company, driven by management with jurisdiction across an entire company. It should encourage managers to work together behind shared goals; in terms of a broader, greater mission."***

Switching Options in an International Market

Lifka pointed out how international markets can provide more flexibility to explore the options for strategic switching.

"The US has the greatest risk exposure because it is usually the largest market, generating most of a brand's revenue," Lifka said. Outside of the US, the cost structure and reimbursement environment means there is not as much contribution at stake, particularly in countries with nationalized medicine.

"The rest of the world presents an opportunity for 100 test markets," he observed. "We can evaluate switch strategies on a controlled scale, with less risk of cannibalizing our prescription business. Plus, the third class of 'ethical OTC' distribution channel outside the US offers us opportunities to evaluate self-care options that may only be much longer term US options."

The pending OTC status of Zocor® in the UK is only the latest example in these differences between national regulatory environments. Non-sedating antihistamines went OTC in many European countries long before the Wellpoint℠ challenge. In Australia, Vioxx® and the cox-2 class went straight to S-3, an ethical OTC category missing in the US. The political and ethical debate around Barr's Plan B® emergency contraceptive has US authorities reexamining the need for a third class.

Help from Top Management

Having made his case for the benefits of a unified, global Rx *and* OTC strategy, Lifka proposed ways that companies can start shifting the paradigm from risk to opportunity.

"Shift the job of setting product goals to a higher level in the corporation, over both Rx and OTC marketing," Lifka suggests. "The OTC extension vision should apply across an entire company, driven by management with jurisdiction across an entire company. It should encourage managers to work together behind shared goals; in terms of a broader, greater mission," he added.

Before setting specific market share targets, Lifka urges top management to think in encompassing terms like leveraging the molecule's lifetime performance in the disease category, across every market segment. "CEOs will embrace the concept of strategic category management," he said, "because it avoids the inward focus that has compromised some switches in the past."

How would this type of visionary thinking apply to a specific drug class? Using statins as an example, Lifka would propose an initial charter to read something like "Pioneer cholesterol management, providing better treatments and broadening consumer access to medicines that will improve the public's cardiovascular health." That's encompassing enough to let the Rx and OTC marketing teams develop category expansion and brand building strategies to deal with internal financial requirements and external factors—reimbursement, government regulation, competition, and importantly, the public health.

Top management's sanction also encourages OTC marketing to add value in early stages of molecule development. The OTC marketer can add value by being the champion of consumer needs – this benefits the patient, but also helps optimize the potential business. "For example, in Phase III, the OTC side can evaluate alternative efficacies, safety claims, and formulations," said Lifka. "That way, you develop options for the molecule that compliment the prescription indications, assembling a portfolio of product variations that can address opportunities throughout the life cycle, instead of limiting yourself to harvesting post-patent sales out of the same dosing or indication." This timing also affords cooperating brand teams the flexibility to allow options in developing product-positioning strategies that can be offensive, defensive, brand building, or country-specific.

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Aligning Goals and Incentives

A combined steering committee of Rx and OTC management allows shared ownership and accountability and encourages alignment on corporate rather than divisional or product specific goals. "To facilitate the change from product management to molecule management, we have to align incentives and accountabilities synergistically between Rx and OTC marketers," Lifka said. He feels that Rx brand leadership should also have its own set of OTC management goals, and vice versa.

Since there are no OTC sales during Rx exclusivity, other goals can be employed to determine incentives, such as reaching specific milestones in the preparation for the OTC switch, no matter how far away it is.

Lifka estimates that currently, OTC switch plans are typically developed five years plus, in advance. “The changing global reimbursement environment is compressing the cycle more towards what we now consider mid-term and short-term,” he said. “To be prepared to respond competitively, team leaders should already be developing switch milestones and decision points at the outset. These benchmarks form a unified gauge to measure both Rx and OTC management performance.”

Lifka charged the conference attendees to "be prepared for molecule management. We are in a period where consumer empowerment has made switching a headline issue. All it will take is one or two marketplace success or failures to instigate substantial changes in switch management dynamics. If you don’t start reworking the internal paradigm yourselves right now, external forces, like your competitors, may rework it for you.”

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