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Assessing future loss of exclusivity scenarios

By Mike Mabey and Gerard Loosschilder, Ph.D.

The forecasting of scenario consequences helps brand teams contemplate "what if" situations regarding market possibilities and alternative courses of action. The discipline and focused thinking involved in scenario forecasting ensures the brand team considers all of the alternatives.

Forecasting allows one to quantify various scenarios to identify the most effective solution for the business moving forward. It is also useful for developing strategies for dealing with worst-case scenarios. Forecasting outputs include the number of prescriptions under a scenario resulting in a sales number, and/or the share of prescriptions to be had across patient groups in the indication area, resulting in a market position.

There are five archetypal loss of exclusivity scenarios that benefit from applied forecasting.

No. 1: A generic launches; how bad will it be?

If a generic Rx launches, insurance companies will usually push their members to switch to the generic version. Even though your brand may count on prescribers' and patients' loyalty, the push creates price and sales pressure. A forecast can help assess the effects of the generic by helping to estimate physician loyalty to your brand for existing and new patients under the new reimbursement scheme. In addition, forecasting will help determine the timeframe for worst-case scenarios and the pressure points where the brand team can develop defensive actions.

No. 2: What about biosimilars?

Biosimilars are officially approved subsequent versions of innovator biopharmaceutical products made by a different sponsor. Their launch follows the patent and exclusivity expiry on the innovator product. Reference to the incumbent brand is an integral component of their approval. For the incumbent, the opportunity is to forecast the cannibalization effect of the biosimilar, or to review options to respond strategically to the competitive launch. For the challenger, the opportunity is determined by the conditions under which the biosimilar or follow-on biologic are launched. For example: Is a lower price enough to sway the market and overcome physicians' loyalties?

No. 3: How can you extend your branded drug's lifetime?

A very relevant type of scenario involves extending a drug's lifetime beyond its patent expiration date by introducing new ways of adding value. One option is to combine drugs and therapies including fixed dose combinations to decrease the pill burden in poly-medicated patients. The number of poly-medicated patients is increasing in many Western countries as the population ages and the prevalence of obesity and lifestyle diseases increases. Another option is to find more comfortable administration methods, such as moving from injectable to oral forms, or administration through proprietary drug-device combinations. Forecasting these scenarios allows the brand team to examine the effects of combination therapies and administration methods on patient retention for the branded drug, and its ability to recruit new types of patients.

No. 4: How does a changing pricing strategy affect the landscape?

Government bodies and payers are seeking new ways of exercising control. This involves a variety of eligibility scenarios for patient groups, copayment and deductible scenarios in payer policies – even different splits in public and private insurance programs. There is an opportunity to explore the impact of pricing scenarios and reimbursement schemes on business performance.

One class of scenarios involves differentiating the drug to target specific patient groups and niches. Those groups can be smaller in terms of absolute business opportunity, but one position may be more defendable than another. The special nature of the drug or its administration, described under scenario No. 3, may allow for reimbursement in spite of the availability of the generic. The forecast helps the brand assess the opportunity because of the size of the patient group and the willingness of the payer and physician to make the drug eligible to this group.

No. 5: Move the brand to OTC or branded generic?

Traditionally, forecasting approaches primarily examined the impact of a complete loss of competitive strategy. However, moving to OTC or branded generic is one way of preserving and/or leveraging brand equity built up over the life of the patent. Decision behavior modeling forecasts allow the brand team to assess the residual value of the brand equity and how long that equity might last. These studies can be executed in two ways: First, one can study patients only, assessing how patients can be enticed to switch from Rx to OTC solutions under variable pricing scenarios (copayment or full out-of-pocket payment), benefit descriptions and administration methods. Second, one can study both patients and physicians to model their interaction and mutual influence. How open is the physician to the patient's questions and request for a drug? How likely is the patient to follow up on a prescription or recommendation? Powerful, new forecasting methods replicate the conversation, helping to achieve a balance between physician push and patient pull.

How to deal with the inherent uncertainty of all forecasting scenarios

As conditions change and market-altering events occur, decision-making data and analogues based on historic events and data may not be available, consistent, or valid. This uncertainty requires approaches that are flexible and work within various scenarios or potentially combine scenarios taking into account the likelihood of a scenario to happen. In addition, the importance of emerging and underdeveloped markets, for which analogues and historic data are not available, is increasing. Approaches that incorporate those uncertainties, such as Monte Carlo, are valuable tools for putting parameters around the uncertainty. Monte Carlo forecasts allow for combinations of scenarios and their likelihood of happening, generating a forecast that supports decision making within uncertain conditions. A traditional forecast produces a single number (e.g., number of prescriptions or revenue), whereas a Monte Carlo type of forecast produces a range estimate accounting for uncertainties in the scenarios. Brand managers can decide what level of risk they are comfortable assuming, as well as the business potential for certain defense scenarios at that risk level.

Forecasting in general is a powerful tool for understanding how the market will change when a drug goes off patent and to assess the effectiveness of alternative courses of action and defense strategies. While very analytic in nature, forecasting is an act of creativity. After all, it takes creativity to envision the "what if" questions and think through the ramifications of the answers. As such, forecasting is a strategic management tool that fosters exploration and builds confidence in potential solutions. The archetype scenarios presented here on one hand help to assess the severity of the situation, and on the other hand help to assess the effectiveness of defense strategies. Mixing them, and accounting for their likelihood of happening, is key to building an actionable forecast.

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FACTS & FIGURES

The average Medicare Part D patient filled **49** standardized 30-day prescriptions in 2010, according to research by the Dartmouth Atlas Project. At the high end, patients in Miami filled an average of **63** prescriptions, compared to patients in Grand Junction, Col., who filled **39** prescriptions per year. Other high-use regions included Lexington, Ky., (**59** prescriptions) and Huntington, W.Va., (**58**), compared to low-use regions in Albuquerque, N.M., (**40**) and San Mateo County, Calif. (**41**).

Nearly eight in 10 heart attack survivors (**78.5 percent**) filled at least one prescription for a beta blocker in the seven to 12 months following a hospital discharge in 2008 or 2009. The results ranged from San Angelo, Texas, (**91.4 percent**) to Salem, Ore. (**62.5 percent**). The pattern of statin use after a heart attack was similar to that of beta blocker use, with **72 percent** of heart attack survivors filling a statin prescription in the second six months after leaving the hospital. The results for statin use ranged from a high in Ogden, Utah, (**91.3 percent**) to a low in Abilene, Texas (**44.3 percent**).

NCQA recommends that survivors of a fracture resulting from osteoporosis should receive drugs that reduce the risk of subsequent fractures. However, only **14.3 percent** of fragility fracture survivors received a drug to combat osteoporosis within six months of their fracture. The use of osteoporosis drugs across regions ranged from Honolulu, Hawaii, (**28 percent**) to Newark, N.J. (**6.8 percent**).

More than one in four Medicare Part D beneficiaries (**26.6 percent**) filled at least one prescription in 2010 for medications that have been identified as high-risk for patients over age 65, such as skeletal muscle relaxants, long-acting benzodiazepines, and highly sedating antihistamines. Patients in Alexandria, La., (**43 percent**) were more than three times as likely to receive at least one high-risk medication as patients in Rochester, Minn. (**14 percent**). **More than 6 percent** of Medicare patients filled a prescription for two or more different high-risk medications.

Spending on prescriptions by the Part D drug plans and their patients totaled **$2,670** per beneficiary. Spending varied nearly threefold across regions, with a **$2,968** difference between the lowest-spending region — St. Cloud, Minn. (**$1,770**) — and the highest spending region, Miami (**$4,738**).

Overall, **26.3 percent** of prescriptions were filled as a brand-name product in 2010. Patients in Manhattan (**36 percent**) were more than twice as likely to fill a prescription for a brand-name product than patients in La Crosse, Wis. (**16.5 percent**).

Is Glaxo keeping its transparency commitment?

By Ed Silverman

For the past year, **GlaxoSmithKline** has vowed to usher in a new era of transparency by creating a system to disclose detailed clinical trial data. This widely publicized move has been hailed by many critics of the pharmaceutical industry who have accused drug makers of deliberately concealing vital information that should be accessible to others in order to confirm safety and effectiveness.

Now, though, a group of researchers is putting the drug maker to the test by requesting detailed data for an infamous study of its **Paxil** antidepressant, but are squabbling with the drug maker over information being sought. In the process, the dispute is raising questions about whether Glaxo complied with a 2004 consent order with the New York State Attorney General to publicly disclose the Paxil trial data.

At issue is data for Study 329. Glaxo participated in preparing, publishing, and distributing what U.S. authorities called a "misleading medical journal article" because the results reported that a Paxil clinical trial demonstrated efficacy in treating depression in patients under age 18, when the study actually failed to make the case. The trial missed its endpoints and also figured in a ghostwriting controversy.

For more than a decade, the study has haunted Glaxo after it became known that suicide risks in what was one of the best-selling antidepressants had been minimized. The episode, which led Glaxo to the 2004 consent order, factored into the $3 billion settlement with the U.S. Department of Justice last year for illegal promotion and pricing activities. For its part, Glaxo maintains it has fully complied with the order.

However, a loose-knit group of researchers led by Jon Jureidini, a child psychiatrist at the Women's and Children's Hospital in Adelaide, Australia, and a professor in psychiatry and pediatrics at the University of Adelaide, is haggling with Glaxo over certain data referred to in the consent order. They maintain the drug maker has balked at their request and raised questions about its commitment to releasing data.

The tussle underscores the ongoing tension over the extent to which certain data – notably, anonymous patient-level data – can or

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