



Can pharma companies really predict the success of new product launches? **Patrick Howie** and **Mike Luby** report on how pharmas can hone in on physicians' actual prescribing behavior versus stated intentions

AN ACE IN THE WHOLE

Imagine your company just spent millions of, if not a billion, dollars and 12 years developing what has been anticipated and hyped as the most promising new drug and the sure next blockbuster. Your job is to get the product to perform equally well, if not better, in the marketplace. You've spent months creating your strategy, positioning and promotional campaign, testing receptivity with your target audiences along the way and, of course, asked physicians if they plan to prescribe the drug.

The good news? Physicians said they would prescribe the drug. The bad news? The prescriptions don't follow.

For years, pharmaceutical sales and marketing brand teams have failed to realize how great a divide exists between what physicians say they will prescribe versus what they actually prescribe. With a wide range of variance between stated intentions and actual prescribing behavior and an inconsistent framework to filter this raw physician demand for other forces in the marketplace, it is no wonder that the pharmaceutical industry has historically faced so many challenges in accurately forecasting the success of a new product.

The joke has been made inside many pharmaceutical companies that the core competency of the company is not launching new products, but rather in re-launching new products. For many years, the "misses" have been covered by the "hits," but with the pressure that the industry is currently facing on so many fronts, every miss is highly visible.

Further, the difference between a hit and a miss is also getting more pronounced, so the concept of re-launching to correct for initial problems is much less viable than it has been. It has never been truer than it is today that "you never get a second chance to make a first impression."

To understand how physicians' stated intentions translate into actual prescribing, we look at the uptake of new products over the last several years in this context. Analyzing launches that have taken place since the beginning of the decade, both in terms of physicians' pre-launch intentions as well as post-launch prescribing, paints a clear picture of the disconnect that is fueling this challenge. And the picture has only gotten murkier over the past three years due to two big marketplace changes: the implementation of the Medicare Part D prescription drug benefit and the guidelines from PhRMA, the industry trade group, recommending limited use of direct-to-consumer (DTC) advertising immediately upon launch.

I don't do as I say

While it is relatively intuitive to believe that intentions in market research are not a perfect forecast of reality, it is striking how much this is the case for physician prescribing. Across the industry, physician-stated prescribing—whether expressed in patient volumes, prescription volumes or share of either of these measures—is generally accepted as a guide to assessing market potential and uptake.

While it is commonly accepted as overstated, there is a widespread belief that it is a good indicator and that it can be adjusted or dampened to account for the overstatement. While there are many factors contributing to the gap between launch expectations and actual performance, the gap in stated intentions explains a

huge portion of the overall gap. An analysis of stated prescribing data for over 75 launches that have taken place since 2002 shows that pre-launch stated prescribing does not predict post-launch prescribing very well.

The scatter plot for stated share of prescribing, based on pre-launch interviews with physicians, vs. actual share of prescribing post-launch for more than 50 drug-specialty combinations yields an R^2 of 0.23. (R^2 is a statistical term that defines how good one term is at predicting another. If R^2 is 1.0 then given the value of one term, one can perfectly predict the value of another term. If it is 0, knowing the value of one term does not help one predict the value of the other term at all.)

One can easily infer the disconnect between these two measures,

Fig. 1: Stated share: "adjustment"

Even in the same therapeutic category, the adjustment factor from stated share to actual TRx Q2 post-launch is marginally different across brands. This data confirms the argument that there is no universal adjustment factor for stated share. Adjustment factors differ similarly in other therapeutic categories.

	Stated Share	Actual TRx Share Q2 Post-Launch	Adjustment Factor Stated Share to Actual TRx
Depression Launch 1	0.060	0.002	0.033
Depression Launch 2	0.109	0.022	0.202
Depression Launch 3	0.155	0.056	0.361
Depression Launch 4	0.096	0.053	0.552
Depression Launch 5	0.137	0.089	0.650

as it is supported by the "R-squared" for the analysis. What is very interesting about this analysis, however, is not just that a gap exists, but rather that the gap is not reliably converted to actual performance by "adjusting" the stated prescribing numbers. Figure one shows the same data differently by focusing specifically on brand-specialty combinations in a single therapeutic category. Using the depression category as an example, the ratio of actual market share to stated market share ranges from 0.033 to 0.65. This begs the argument that there is no universal adjustment factor from stated market share to actual market share, even for brands in the same therapeutic category. As figure one shows, the ratios are all over, so there is no standard way to "adjust" the share provided prior to launch. The fluctuation in adjustment factors in depression is similar to that seen in other categories as well. Clearly, there is no discernable pattern for the many instances of multiple launches in the same category.

I can tell you what I am going to do, but you have to ask the right questions

Extensive modeling and exploratory research has been done in an attempt to "clean up" stated share and improve the prediction of launch uptake based on interviews conducted prior to launch. Exploratory research has been conducted over the past 10 years to determine whether other questions that could be asked in research conducted prior to launch could help to more accurately explain

launch uptake. After initial exploratory research was conducted, it appeared that questions that would help to calibrate each individual physician's responses offered the best hope in this area.

Factors such as anticipated time to adoption, physician opinion on the degree of innovation the new product offers and others have served as valuable inputs into a predictive model to improve pre-launch opportunity forecasting.

The scatter plot of modeled predicted share vs. actual share of prescribing post-launch boasts an R^2 value of 0.796, which illustrates the value of this predictive modeling process. This "cleaned up" stated share of prescribing, based on pre-launch interviews with physicians but modeling in several other factors beyond stated share, is a much better predictor of actual share of prescribing post-launch. This R^2 value of 0.796 is based on the same exact set of 50 drug-specialty combinations used in the analysis of stated share vs. actual share (which yielded $R^2 = 0.23$).

An improved predictive modeling process can dramatically improve the ability to forecast adoption, but that is only a small part of the problem. The problem is compounded because the positioning is often determined indirectly by the flawed forecasting process. Many positioning approaches assess the value of a products attributes by doing a derived importance-type exercise through which regression analysis is utilized to determine which attributes are the biggest drivers of product adoption. The difficulty with this approach is that the "yard stick" to measure success against is the stated share which has been shown to be overstated and unreliable. So the same error that is driving the forecast often gets applied to determining the optimal positioning for the brand, which compounds the problem at launch. Consider the example of an inhaled insulin product launched recently in the US and later withdrawn due to significant under-performance relative to expectations.

Pre-launch stated share indicated that the product would be rapidly adopted and assessment of positioning indicated that the availability of an inhaled dosage formulation of insulin, which would not require injection, would be a highly valuable attribute to serve

The data referenced in this article

The data used in the analysis comes from both primary and secondary sources. The secondary data used comes from a prescription claims database containing a representative sample of retail/office-based prescription claims from the period of 2002 through 2008 that were analyzed. From this database, more than 300 launch curves were developed based on a product by specialty cut of the data. So, for example, the uptake of Crestor among cardiologists would be on of the 300 launch curves, separate from uptake of Crestor among primary care physicians.

The primary data comes from the TargetRx database, an extensive attitudinal database containing survey responses from physicians. The attitudinal data set contained information from physicians from more than 200,000 surveys on a wide range of topics relating to physicians interactions with patients, perceptions of products, awareness and perceptions of payor activities and their participation in and reactions to pharmaceutical company promotion. Attitudinal data were assessed for over 150 pre-launch brands and over 500 marketed brands over the period of 2002 through the end of 2008.

Fig. 2: Brand positioning: stated vs. derived

Product Attribute	Derived Against Physicians' States Share		Derived Against TargetRx Precicted Share	
	Importance To Brand	Order	Importance To Brand	Order
High AV potency:	1.04	6	0.50	1
Not for highly treated:	2.27	2	0.48	2
For resistant patients:	1.52	5	0.47	3
Treats high viral loads:	1.85	3	0.44	4
Low metabolic SE's:	0.89	8	0.43	5
Treats low CD4:	2.66	1	0.41	6
First Line:	1.63	4	0.38	7
Sustained response:	0.57	10	0.36	8
Low GI toxicity:	0.92	7	0.30	9
Second line for NNRT:	0.59	9	0.25	10

as the basis for a strong positioning in the marketplace. But the product never caught on. In hindsight for this specific case, predictive modeling of the pre-launch measures shows that the marketplace was going to be very hesitant to adopt this approach.

An example to illustrate how the forecasting error compounds the positioning is shown in figure two. On the left is a derived importance of attributes utilizing physician stated market share from over 100 physician interviews prior to launch, with the attribute numbering representing the importance each attribute will play in differentiating the product in the marketplace and driving adoption. This is real data for an HIV therapy that was launched in the past few years.

The data on the right table two shows the same analysis, with the brand attributes listed in the same order, but instead of physician stated share, the yard stick of success is the share derived from the predictive model incorporating a series of other factors to improve the accuracy of stated share. This analysis highlights the difficulty quite clearly. A brand team guided by stated share will emphasize the attribute, "Treats low CD4" as a top priority (ranked #1 against stated share), whereas the predictive modeling would send that same attribute after five other attributes deemed more important to the success of the launch. As you can imagine, the message platform and entire marketing campaign is going to be very different based on the approach utilized.

Predictive modeling offers opportunity for improvement

Considering the dynamics of today's pharmaceutical marketplace, the stakes for new launch brands could not be higher. R&D productivity is not what it was 10 years ago. The FDA environment has tightened considerably, and physicians, payors and patients are all reacting more conservatively to the "post-Vioxx" world. At the same time, the last generation of blockbusters is rapidly going generic, providing safe, effective, trusted options for many diseases.

So, failure is not an option (it never is, but you could survive it 10 years ago). There is an opportunity to improve upon the traditional approaches to forecasting and positioning, utilizing predictive modeling approaches to better assess uptake and to link the improved understanding to the development of positioning. ■

Patrick Howie, is senior vice president of product development and marketing, TargetRx and Mike Luby is the co-founder of TargetRx

