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Maximizing Value in a Reimbursement Sensitive Market

By Dr. Robert C. Keefer

Virtually everyone with a new product in our industry would love it if they could command premium pricing. To that, we say why not? We all know that R&D costs for pharmaceuticals and medical devices are among the highest, if not the highest, of any industry. We also know that because of the high rate of R&D failures, each new-marketed product has to bear the cost of all the other failures along the way. Finally, any developer of any new innovative product that solves an important medical need in a more cost effective way *should* be able to value price the product. Right?

Well, yes, that makes sense until the realities of today's payor market and physician preferences and economics hit home. It is because of them, and because of the high stakes involved in introducing innovative new products to the market, that the developers must build product value accurately and well in advance of product launch. Even companies planning to out-license a product to a marketing partner should do that particular work themselves. If they do— rather than passing it on to the marketing partner — they can support higher valuations and sales forecasts in negotiating the deal and working downstream with the partner.

To help you think about this, we call your attention to the report that Janssen-Cilag made a creative "guaranteed or your money back" offer to the UK reimbursement agency, National Institute for Health and Clinical Excellence (NICE), to cover the complete cost of a new oncology drug if the patient does not benefit from it. While this was a special case involving a drug with a way to measure efficacy, it's a great example of how to develop a relationship—and a brand—with critically important customers by first understanding and then meeting their needs.

The story reminds us once again of how success or failure in understanding the specific dynamics of how payors, physicians and patients are affected by reimbursement will make or break a product. Each therapeutic area and each

product is different, of course, but let's look again at critical care, oncology drugs and medical devices as prime areas for learning lessons.

Injectable oncology drugs and many medical devices must be administered by trained health care practitioners. Instead of the patient going to the drugstore and dealing with reimbursement or drug co-pay issues, the physician buys the product and files for reimbursement directly from the Centers for Medicare & Medicaid Services (CMS) and other payors (many private groups follow the CMS lead).

From the physician-as-customer perspective, cumbersome paperwork, inadequate reimbursement or reimbursement delays caused by CMS coding issues will affect their motivation to dispense a particular drug or use a medical device. Furthermore, if the physician isn't given data that shows a clear medical and economic benefit to treating the patient with the new product, he or she may not — and usually does not — use it, especially if there are alternative therapies. The patient loses the benefit of the new treatment and the marketer loses a sale.

The Janssen-Cilag experience with NICE is a good example of the kind of creative, proactive step a company can take to ensure a successful product launch *if* the company has done its homework and established a working, and positive, relationship with the payor.

We can't claim to know the back-story that led the company to make its bold offer to NICE, but we can make a few assumptions and give you some tips on what to do as a Brand Manager to lay the groundwork for payor support.

1. Put great marketers on the job and start them early: You must have a definitive plan for interfacing with CMS an average two years in advance of product launch. Do your people know the timetable for securing new CMS codes for new drugs? Do they know the impact on the physicians' treatment practices if the coding isn't established at product launch? Have they anticipated the different kinds of unexpected requirements and delays that can be caused in reimbursement processing, and do they have the solutions for all eventualities that could affect a successful product launch? Do they know which payors will be influenced by pharmacoeconomic data and do they know how to get this information to them? Do they know how many and which ones of the payors use specialty companies to broker or actually handle the type of products you plan to launch? Do they know what reimbursement your product will qualify for, and how it will be calculated under the new CMS policy of determining Average Sales Price? Have you anticipated how long it will take to engage and fully implement a publications plan to support your approaches to payors? Do you have a plan to deal with all the possible market decisions and nuances that are known, and even a contingency plan for those you haven't anticipated or that come up after your process starts? Have you factored all of this into your sales forecasts?

2. Generate quantitative data: By starting early and dedicating yourself to understanding what the customers — including payors, physicians and patients — want and need, marketers and brand managers can gather information on what additional data is needed in the Phase 3 clinical trials. If you like the advice given above, define the endpoints and data that should be collected to prove the value of the new drug or device. This information is critical to your ability to value price the product and help fund R&D on the next products. Further, to develop the model, make sure your marketers take into account the costs and impact on:
 - Physicians and nurses. For example, do you know and have you collected data on infusion and patient interaction times?
 - Patient quality of life and costs. Will your product allow the patient to go back to work and experience fewer adverse side effects and need fewer ancillary prescriptions? Have you collected the data so you can legally use it in your product promotion plans?
 - CMS and other payors. What will be the economic impact on those agencies that might otherwise have to fund the purchases of other prescriptions and procedures if your product isn't used?
3. Communicate the proof in a way that your customer will understand it: If economic data is collected along with medical data in the clinical trials, marketers can present this proof to the CMS (with enough time for them to act positively) as well as to other payors and in product communications to physicians and patients, too. Remember, rightly or wrongly, most new products are perceived as delivering incremental value over the older products and customers make the final decisions. Make sure you are delivering information that they need to justify their decisions.
4. In your pricing strategy, account for differences in U.S. and international markets: Pricing strategy needs to account for what international payors will reimburse, and in the U.S. for the extent of discounts, rebates and sampling programs, promotional strategy, manufacturing costs, anticipated lifecycle management issues, anticipated product line extensions and reformulations, etc.

Marketers of all products in this industry must comprehensively address all of these issues well before Phase 3 trials are started — usually two years prior to product launch and even earlier for drugs the FDA has admitted to its fast track approval process. If they are improperly or inadequately addressed, your product will not stand out from the crowd which means launches and sales falling short of the goal.

If you would like to share your experience in these issues, or discuss how you can ensure a successful product launch, send an email to rkeefe@tcgbiopharma.com.

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UPCOMING EVENTS:

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An excellent business development opportunities event for partnering with early stage, emerging biotechnology and biomedical device companies for the pharmaceutical, venture capital, and finance sectors. Last year over 1200 international delegates attended BPE, participating over 4000 one-to-one meetings which were facilitated through biopartnering.com, state-of-the-art partnering software. For full details and Early Bird rate (until August 31, 2007) please see: <http://www.techvision.com/bpe/registration/>

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