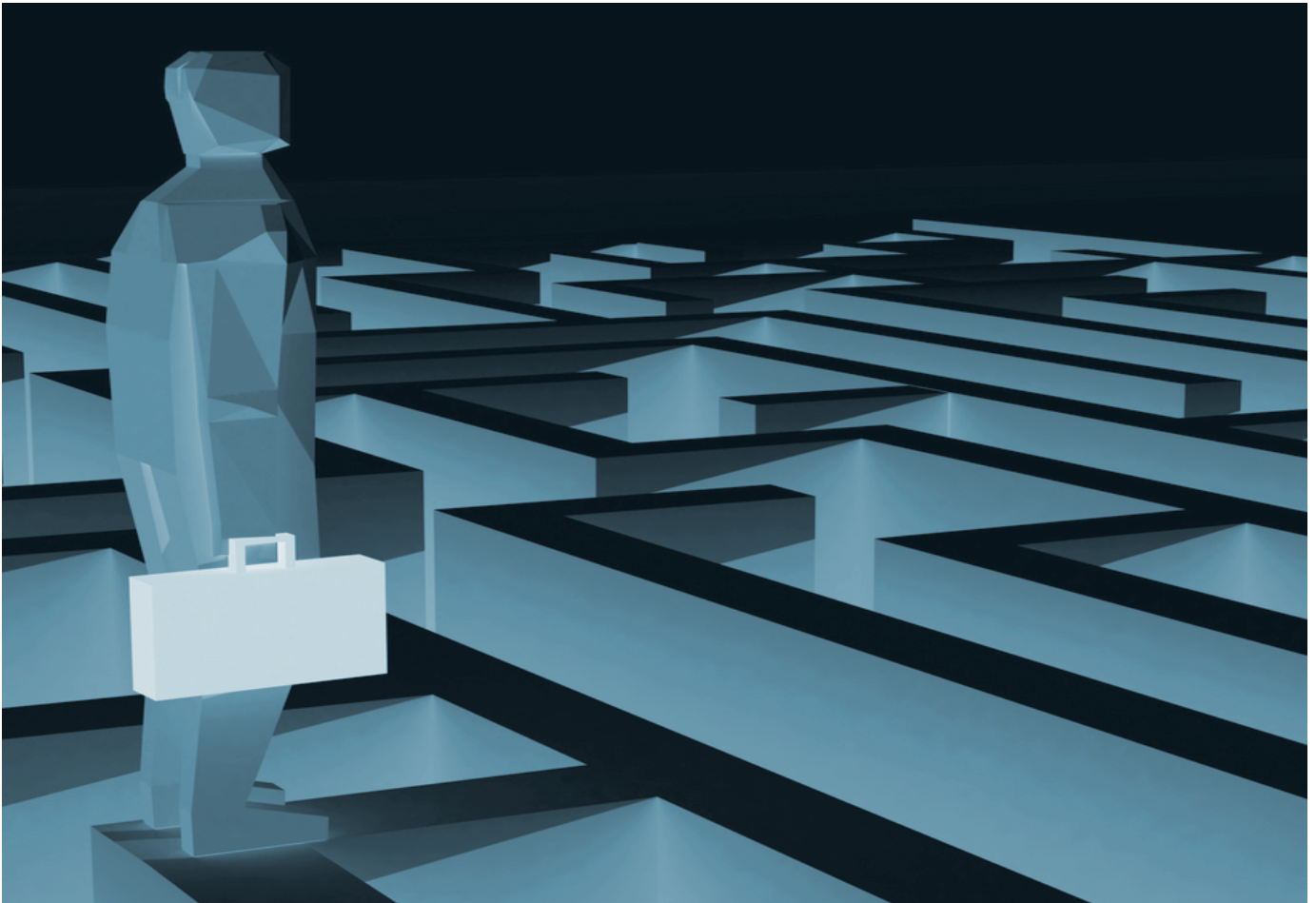


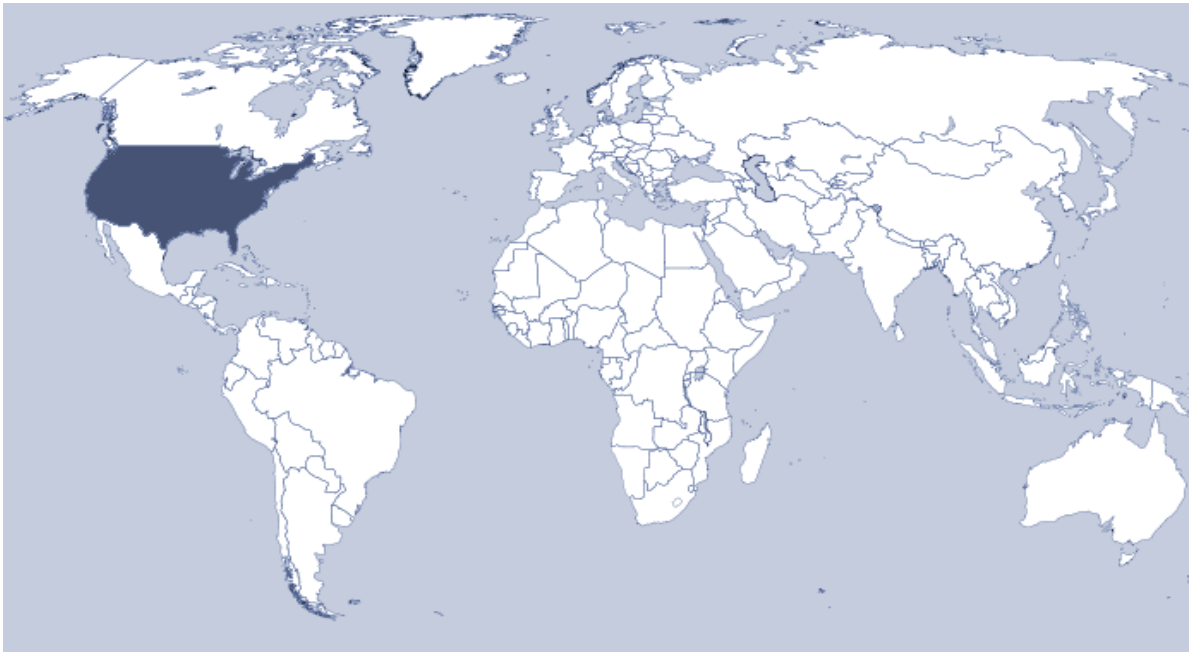


WHITE PAPER



Maximizing Value in a Reimbursement Sensitive Market

by Dr. Robert C. Keefer



Pricing of pharmaceutical and healthcare products is a critical issue in marketing all over the world. This White Paper focuses on the process in the US.

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?

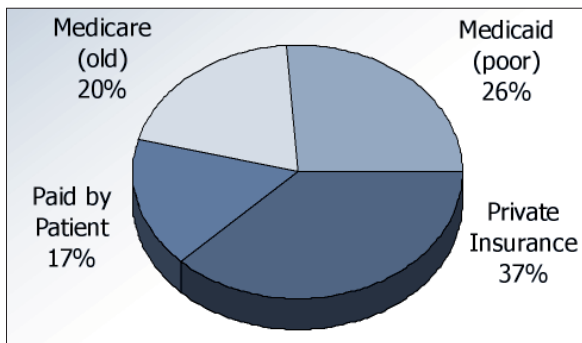
Well, yes, that makes sense until the realities of today's payor market and physician pref-

»Developers must build product value well in advance of a product launch.«

erences and economics hit home. It is because of them, and because of the high stakes in-

volved 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.



Reimbursement from Payors in the US. Although the private groups have their own approval process, they often rely on decisions made by the CMM (Center for Medicare & Medicaid) for public cost coverage.

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, espe-

cially 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

»Understanding the dynamics of reimbursement will make or break the product.«

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



© Guido Schmidt - Fotolia.com

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.

In your pricing strategy you have to account for differences in U.S. and international markets.

Editor:

Dr. Robert C. Keefer

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

rkeefer@tcgbiopharma.com

Publisher:

This white paper is published by TCG LLC of Research Triangle Park, NC.

To keep in touch with the latest developments and for more information, please call 919-941-0700 or see our website:

www.t-c-group.com