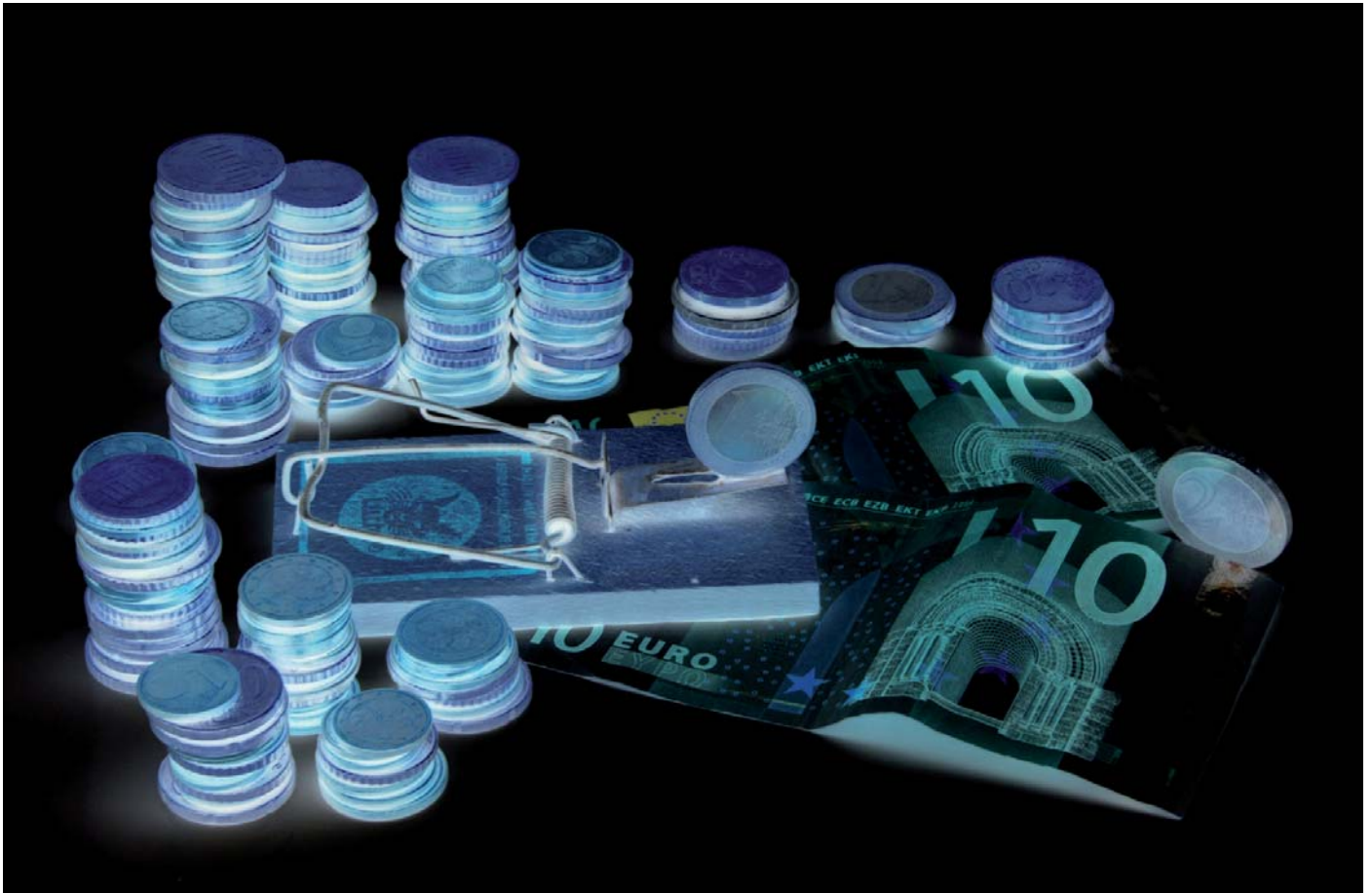




WHITE PAPER



Treasure Chest or Trap?

The U.S. Market for Foreign Life Science Companies

By Dr. Robert C. Keefer

You don't have to be involved in the healthcare industry to know instinctively that the U.S. market presents huge opportunities for just about any pharmaceutical or medical device that a company could create. So why do we read about a great product developed by a foreign-based company that is marketed suc-

»It starts with the decision to gain a good understanding of the buying patterns of your customers.«

cessfully everywhere in the world — except in the United States? Why would these companies not want to get into this treasure chest of healthcare consumers?

The simple answer is that companies that stay away from the U.S. market see this market as a risky proposition in terms of the marketing costs and the potential for product liability lawsuits. But is their assessment correct? Here is what we think:

The reward is many times greater than the risk: Recent data indicate the market remains an exceptional opportunity for growing firms with superior products. The U.S. medical device/diagnostics and pharmaceutical segments remain the largest and most profitable in the world, exceeding \$100 billion each. On top of that, demand is growing due to an aging population and willingness on the part of regulators and health insurance companies to approve and adopt superior products that save money for the healthcare system.

Finally, history shows us that this industry has never been negatively impacted in past U.S. recessions, and recent data supports the fact that these consumer-driven markets are as strong as ever even now.

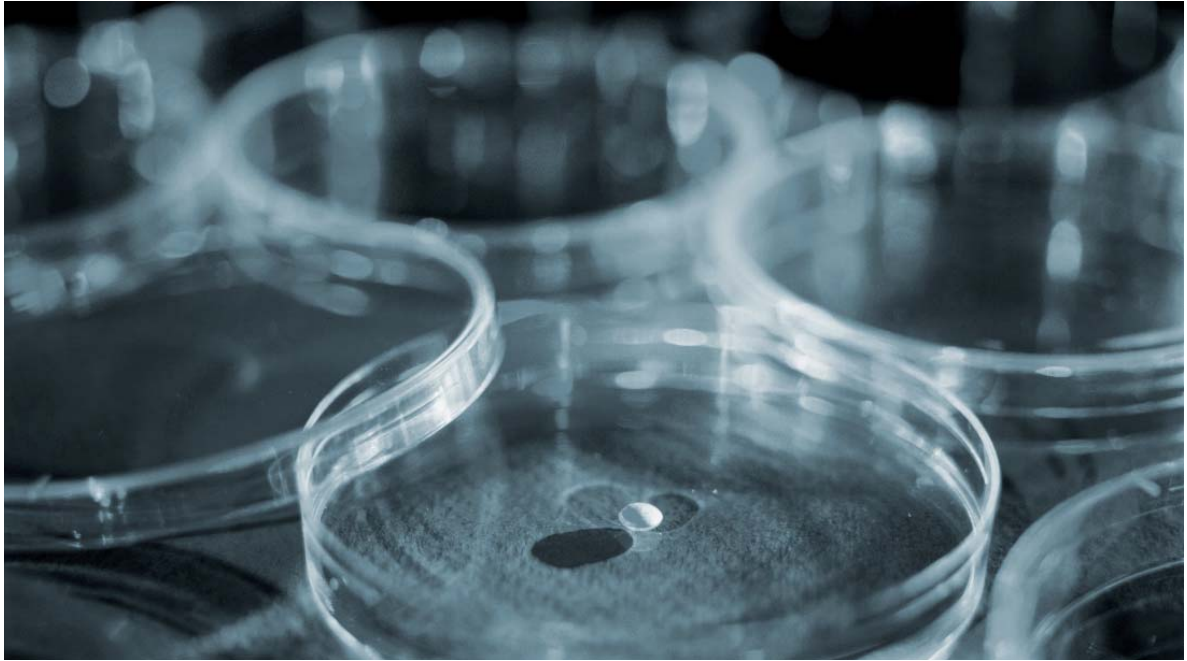
Distribution networks handle sales: Many overseas companies look at the vastness of the U.S. market and see the development and management of a large sales force as an overwhelming — and extremely expensive — obstacle. They think they need to hire and train an army of sales people when in reality they simply need to plug into this country's existing distribution network.

There are hundreds of experienced distributors covering all healthcare specialties and regions of the United States offering an impressive list of sales and marketing services. Employing the right distributors to market your product means no capital outlay or salary expense on your part and only a fraction of the marketing expense. So how do you find the right distributor(s)?

As always, it starts with the decision to gain a good understanding of the buying patterns of your U.S.-based health care customers: how they make decisions, who they currently buy from and why, how to best reach them and how to reach them at the lowest cost. Getting that information is inexpensive because it does not require exhaustive market research. It does require expertise to know what questions to ask and to whom, but even more important is getting the information at least 4-6 months before market launch so you can make good cost effective decisions.

At the same time you can quickly learn the names of the quality distributors who call on the customers you most want to have. Then talk to those distributors and find out which other distributors they trust and deal with in other regions. Through this process you can put together a customized distribution network and a targeted launch plan using the best meetings and trade shows, as well as all the other standard market launch tactics.

Legal protection: The United States, rightly so, has a reputation for being a society that



The „Treasure-Chest-Point-of-View“: If your product line is strong and innovative, there are lots of ways to grow your business in the U.S. healthcare market. Buy experience where you need it.

virtually encourages frivolous lawsuits designed only to extract money from large corporations. No company wants to risk its reputation and assets when they see the potential for unwarranted lawsuits.

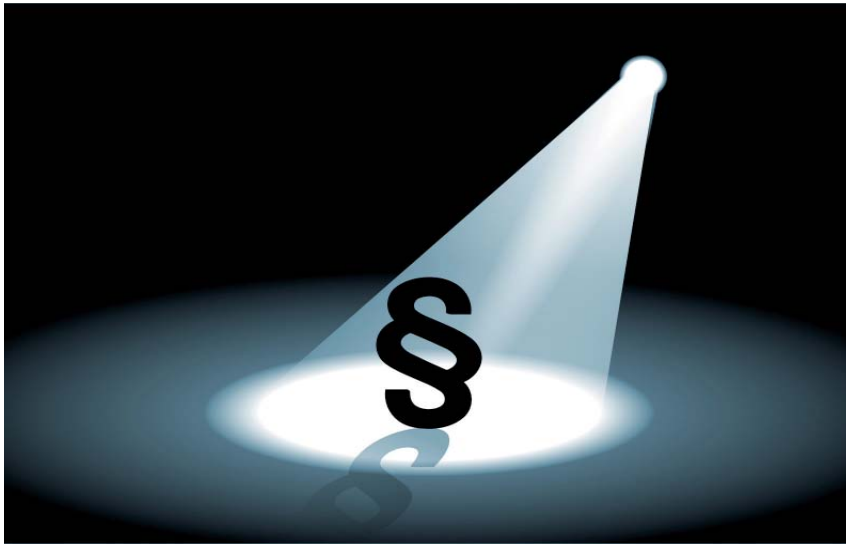
Of course, nothing can protect you if your product does truly cause harm, but if your product is FDA-approved and has been used safely elsewhere in world, you won't be in any greater risk here if you have the right contracts in place and follow a few other wise precautions. Furthermore, creating a U.S. subsidiary with certain specific corporate legal paperwork can protect the assets of your overseas parent company.

In addition, there are many experts who can help you ensure that your advertising and marketing materials do not overstate your product claims and that your distributors are training your customers on its proper use. This will also help you avoid any FDA regulatory issues particularly in terms of expanded patient uses, which has become a hot issue in the United States for budgetary as well as legal reasons.

Reimbursement issues: Foreign-based companies tend to think that U.S. health insurance and reimbursement policies and processes are too complicated to deal with and create more problems than they are worth. This is a misconception. The truth is that a good cost effective reimbursement program can ensure your products' success, and the key is to simply think of them as your customers.

»A good reimbursement program can ensure the success of your product.«

Branding can be “everything”: If we may make a general observation, consumers in other countries — particularly in Europe and Japan — are more practical and fact-oriented when they choose healthcare products. They pay more attention to the product features and benefits and are less likely to be influenced by brands and how a product is



The „Trap-Point-of-View“:
Nothing can protect you if your product is harmful. But if it is FDA-approved and used safely elsewhere in the world, you only need the right contracts in place and to follow a few wise precautions.

presented. Here in the United States, we are more likely to be influenced by a product’s advertising or a clever slogan, and may make a purchase decision based on that rather than the lengthy product description.

This doesn’t make the U.S. market more difficult to penetrate — just different. Companies who have successfully marketed in other countries simply need to pay significant attention to brand, positioning statements and advertising to ensure success in the U.S. market.

Devalued dollar benefits foreign companies:

With the end of the financial market crisis in sight and the U.S. elections a few months off, a stronger dollar is likely in the next year or two. That means now is a good time to invest in a U.S. product introduction to take advantage of the favorable exchange rate, the Dollar has at the moment.

Launching a product in the United States is the cheapest it has been in a decade. As an example, filing a 510k with the FDA in 2003 cost €\$3,900; today it costs only \$2,700. The differences for PMA and NDA filing fees are even more dramatic. Journal ads to launch a product are 35% less and an exhibit booth at a major medical tradeshow or meeting can be only €\$2,000 versus €\$3,000 in 2004. Travel costs to meet potential U.S. distributors or key medical and scientific opinion leaders are at a 35% discount and, finally, you can achieve significant savings by using U.S.-based industry experts to de-risk your U.S. business even more.

So to those companies that say the U.S. market is a risky proposition, we say sure there is risk and issues unique to the U.S. market. But if your product line is strong, now is the perfect time to cash in.

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To get more information on the U.S. healthcare market and to keep in touch with the latest developments please call +1-919-941-0700 (in North America) +49-6221-27262 (in Europe) or visit our website:

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