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BioMarketing Insight Newsletter

Creating Markets and Marketing Strategies

Dear Regina,

Welcome to BioMarketing Insight's monthly newsletter.

Last month I covered "From High Tech to Med Tech." If you missed last month's article, click here to read it. This month will cover "Market Access, What It Means and Why It's Important."

Read on to learn more about this topic and other current news. On the right are quick links to the topics covered in this month's newsletter. The next newsletter will be published on April 15th.

We encourage you to share this newsletter with your colleagues by using the social media icons at the top left, or by simply forwarding the newsletter via email.

Please email me, Regina Au, if you have any questions, comments, or suggestions.

Sincerely,
Regina Au
Principal, Strategic Marketing Consultant
BioMarketing Insight

In This Issue

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The Paradigm Shift to an "Open" Model in Drug Development

I'm pleased to announce that my article "The Paradigm Shift to an 'Open' Model in Drug Development" was published in the December 1st, 2014 issue of Applied and Translational Genomics Journal. To read an electronic version, please click here.

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Save the Date: Medical Informatics World Conference - May 4-5, 2015

At the Medical Informatics World Conference, I will present "Designing Your Wearable Technology with Mobile Apps: What is Needed for Successful Product Adoption and Impact."

Wearable technology with mobile apps will become the norm in monitoring patients' vital signs at home or at work for diagnoses, alerts, management, or treatment of diseases. Getting product adoption from all stakeholders (patients, physicians, other healthcare professionals, etc.) involved with these devices can be difficult unless the device meets their needs and demonstrates significant benefits to them. Learn the rationale behind what motivates each stakeholder, plus the must-have attributes to incorporate that lead to successful product adoption.

I invite you to hear more details on the subject on Tuesday, May 5th at 9:25 AM under Track 5, Leveraging mHealth, Telehealth and the Cloud. For more information on this track click here. For conference details, click here. As my guest, you are entitled to a $200 discount off your registration. Click here for the code.

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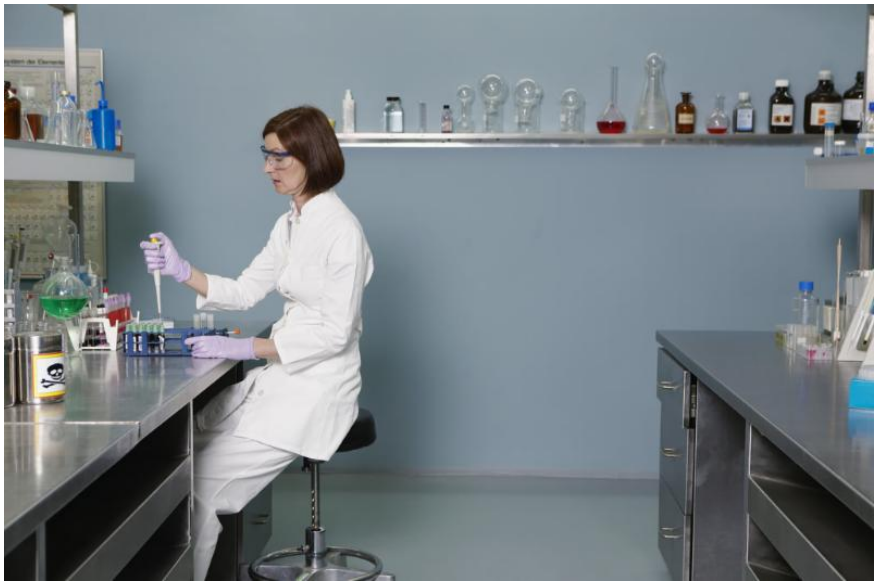
Developing a Product? Need a Commercial Strategy for Product Adoption?



If you are developing a product and have not conducted the business due diligence to determine commercial viability or success, contact me for an appointment. For successful commercial adoption of your product, contact me for an appointment.

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Market Access: What It Means and Why It's Important

What does market access mean?

The term market access basically means how does the patient get access to a manufacturer's drug, biologic, device or diagnostic test as prescribed by the patient's physician?

For example, when you get a prescription from your physician, you go to the pharmacy to fill the prescription and if your insurance covers that medication, you pay a co-pay set by your insurance provider depending on your plan and you receive your drug.

Achieving Market Access.

The difficulty comes when your insurance does not cover the medication. One of two things happens:

1) You pay out-of -pocket for the medication. The price you will pay is the actual retail price which is significantly higher than the insured price.

or

2) You must request from your physician a "prior authorization" to make the case as to why it is medically necessary that you must have that drug. Then the pharmacist at your insurance company will say yes or no to coverage. If the answer is yes, you will generally have to pay a third-tier price, which is the highest co-pay set by the insurance company. First-tier is generics, second-tier is covered brand drugs and third-tier is non-covered brand drugs, which can range in co-pays anywhere from $60 -- $100+ a month, depending on your plan.

Tier pricing exists because the insurance companies have stated that the rising cost of healthcare is unsustainable and this is a way of controlling the cost of drugs for this specific example. This is why generic substitution is mandatory and why insurance companies have "Formularies" (covered drugs), which are used to pressure pharma companies into discounting their drugs. Otherwise they are not covered. For drugs under Medicaid, there is an automatic discount or cap as to what a manufacturer can charge.

This is very common practice, particularly when there are a number of drugs within a category, such as beta blockers or calcium blockers for hypertension. When Gilead launched Solvadi, their Hepatitis C drug, there was heated debate around whether or not insurance companies would cover the drug, because they felt it was too expensive, or limit the coverage to those who did not respond to other meds or reserved for the most severe cases. In hindsight, what Gilead initially didn't make clear was that Solvadi cured the patient of Hepatitis C and a lifetime treatment is no longer necessary. For the insurance companies, the cost is a one-time treatment for a cure, verses a lifetime of maintenance therapy.

Why is market access important?

If you work for a large company, your employer provides health insurance as one of the employee benefits and usually the health plan is very good, what Obamacare calls a "Cadillac Plan", or high-end premium health insurance plan. The co-pays, deductibles and employee contribution to the plan are comparatively low. Cadillac Plans are proposed to have a 40% excise tax by Obamacare, which means that some employers might downgrade to plans that have higher employee co-pays, deductibles and out of pocket expenses. If the employer keeps the Cadillac Plan, the employee will have to contribute more, to cover the cost of the excise tax.

If your income is classified as below the federal poverty level, you are fully covered under Medicaid and have low co-pays.

But if you are self-employed, work for a small company, earn only minimum wage, work part-time, or make middle class wages and don't qualify for poverty level income subsidies, it may be difficult to afford the insurance premiums, co-pays, and deductibles. Despite Obamacare and "affordable" insurance, there are millions of Americans who are struggling to make ends meet and find it much cheaper to pay the penalty for not having insurance. And now, there is a debate as to who will subsidize these "affordable' insurance plans? The federal government is putting the onus onto the States.

Poor compliance, or not taking one's prescribed medications, is one of the biggest factors as to why patients don't get well, or sometimes get worse, due to complications for acute or chronic diseases. Treating these complications contributes significantly to our rising cost of healthcare. One reason that people don't take their medication is they can't afford to fill the prescription. They can't afford the co-pay, or they must pay full retail price because they don't have insurance. Or the medication isn't covered by insurance at all.

There may be other compliance factors, such as an inconvenient dosage schedule that leads patients to forget to take their meds. Intolerable drug side effects will frequently cause patients to stop taking their meds, but cost is at the top of the list.

In response, some pharmaceutical companies have set up various programs and special offers such as coupons, to defray some or all of the prescription cost to the patients. In the case with Gilead's Solvadi, the company cut a deal with the French government to cover Solvadi 100% for patients taking the drug and if Solvadi is found to be ineffective, Gilead will reimburse the government in order to allow patients initial access to the drug.

For cancer drugs, market access to patients is more complex. For certain types of breast cancer, we have information to the genes or biomarkers (BRAC1, BRAC2 and HER2) involved, in order to prescribe targeted therapy for that type of cancer. But there are many cancers we don't know enough about, or have not been able to identified any good targets that play a key role in cancer cell growth and survival in order to develop effective drugs against these cancers. Unfortunately, majority of chemotherapy agents destroy both cancer and healthy cells. It's a trial and error to determine which chemotherapy agent will work. Any new cancer drug that is approved is normally more expensive (due to the rising cost of developing a drug) than the other drugs already on the market.

Until we are in the age of personalized medicine, when there are diagnostic tests and treatments for the majority of diseases it's still trial and error, which is why the insurance companies generally will not cover new drugs until the patient has tried everything else. There are times when insurance may still not cover the new drug, depending on the insurance plan (the lower the premiums, less coverage and more out-of pocket cost). Insurance companies will always start with the generic drugs because

they are the cheapest and then work their way through all the drugs on their "Formulary" before they will consider new alternatives.

In the meantime, the patient suffers through yet another course of treatment, which may fail. This scenario applies to all diseases not just cancer. In response to this many pharma, biotech, diagnostic companies are developing companion diagnostics and treatment, or theranostics, that tell clinicians which drug a patient will respond to or not respond to before the patient takes the drug.

Thinking "out of the box," Medicine 360, a non-profit pharmaceutical company, is taking a different approach to market access, particularly for low-income women. Medicines360's mission is to eliminate the cost barrier for women's access to birth control. Medicines360 and Actavis have a partnership agreement to make the Intrauterine Contraceptive Device (IUD) available in the U.S. commercially and for public sector clinics, it will be available at a very low price. Actavis has licensed the U.S. commercial rights for the Medicines360 LNG20 (IUD) approved by the FDA and Medicines360 retains rights to market the product in the U.S. public sector, including family planning clinics that provide services to low-income women. All monies received by Medicines360 from this partnership will go towards driving down the product's cost in the public sector and future product development, along with educational programs that will increase awareness and contraceptive access for all women.

The company working as a non-profit gives them the financial flexibility to operate and direct profits towards more resources that give women access to birth control. The partnership with Actavis gives them the funding to operate as a nonprofit.

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Closing Thoughts

For medical manufacturers, it is now more difficult for pharma/biotech and device/diagnostic companies to get a drug or device to patients. When developing a drug/device, one must keep the unforgiving new reality at top of mind at the start of the product development cycle. New drugs with only incremental value will not be reimbursed and significant discounts will be required for them to be accepted onto the insurance companies' formulary.

Devices and Diagnostics are reimbursed under a class category, but most new device/diagnostics cost more than what is being reimbursed under the existing class category and Center for Medicare & Medicaid Services (CMS) keeps cutting the reimbursement. On the product adoption side, if the product is not superior to existing products available on the market, stakeholders have no reason to use your product.

The FDA drug pathway also requires comparative effectiveness clinical trials and drugs can no longer be compared to placebo, but rather to the current standard of care, raising the bar even higher. For devices, the 510(k) regulatory pathway is easier than a Premarket Approval (PMA) for innovative devices. However, this technically puts the device in an incremental value category, as opposed to a PMA, and it becomes more difficult to convince stakeholders of the value of using a new 510(k) product.

The Accountable Care Act and the proposed global payment has also set the bar higher, because not only does the product need to demonstrate better outcomes than current products on the market, but also the insurance companies want to see cost savings to the healthcare system, both short-term and long-term.

Companies need to start early and develop a market access strategy that is part of your overall commercial strategy, because the go-to-market process now requires more long range planning, collaboration and coordination across departments in the company, use of data analytics for stakeholders, modeling of various scenarios, and external partnerships where applicable to overcome

these hurdles.

Have any questions or need assistance in developing market access strategies? Click here to contact me.

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New Technology - "Just A Bit Of DNA Helps Explain Humans' Big Brains"

Scientists at Duke University Medical School have found one stretch of human DNA that can make the brains of mice grow significantly bigger. "It's likely to be one of many DNA regions that's critical for controlling how the human brain develops," says Debra Silver, a neurobiologist at Duke University Medical School.

The human version of a DNA sequence called HARE5 (inserted into this mouse embryo) turned on a gene that's important for brain development. (Gene activity is stained blue.) Source:Silver Lab/Duke University

It could also help explain why human brains are so much bigger than chimp brains, says Silver, who notes that "there are estimates of anywhere from two to four times as big." In addition to having bigger brains, Silver says, humans also "have more neurons, and we have more connections between these neurons."

"What we discovered is that the human DNA turned on gene activity in neural stem cells, and these are cells which produce the neurons of our cerebral cortex," says Silver.

Katie Pollard who studies human and chimp DNA at the Gladstone Institutes and the University of California, San Francisco says most of the genetic differences between humans and chimps are actually found in the so-called junk DNA, Pollard notes. "While it's now pretty easy to find the genetic differences, it's very challenging to figure out exactly whether those differences made a change in a trait, and why."

"We can now actually generate the equivalent of embryonic brain cells and tissues that are human or chimpanzee," says Pollard. "And, using genome engineering techniques, we can start to study the effects of switching the human and the chimp sequences in these primate cell lines."

Eventually, work like this could generate a list of DNA sequences that give a brain some capabilities that are characteristically human. That could be important for understanding what goes wrong in diseases of the brain.

To read the full article from *NPR Health*, click here.

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About BioMarketing Insight

We help companies de-risk their product development process by conducting the business due diligence to ensure that it is the right product for the right market and the market opportunity for the product meets the business goals of the company. We can then develop marketing strategies to drive adoption for the product.

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