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Creating markets & marketing strategies

Newsletter

March 15, 2015

Dear Regina,

Welcome to BioMarketing Insight's monthly newsletter.

We have a new mobile friendly newsletter. Love to receive your feedback.

Last month I covered, Five Important Reasons Why Product Adoption Must Be Incorporated into Product Development. If you missed last month's article, click here to read it. This month's newsletter will cover, New Legislation Regarding Pharmaceutical Pricing

Read on to learn more about this topic and other current news. 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, or by simply forwarding this newsletter or use the link at the bottom of this newsletter. Should you or your colleagues want to join my mailing list, click on the icon below or scan the QR code.

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

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Developing a Product?
Commercializing a Product?

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 or looking to grow your business, contact me for an appointment.

For more information on our services, click on the links below:

Product Development
Market Development
Marketing Strategies

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Save the Date: April 4 - 5, 2016
Medical Informatics World Conference

Fourth Annual
Medical Informatics World Conference 2016
April 4 - 5, 2016 Boston, MA
Improving Outcomes and Delivering Value with IT Innovation

A must-attend industry event for senior-level executives and industry leaders all focusing on the new era of healthcare. More than 400 providers, payers, technology providers, biomedical scientists, academic researchers, informaticists and national health organizations come together to discuss emerging trends and collaborations in health IT for improved outcomes in the healthcare ecosystem. For more information on the conference and to register, click here.

I'm also pleased to announce that I will be co-moderating one of the interactive breakout session entitled "Improving Health and Reducing Costs through Traditional and Innovative Approaches to Coordinated Care and Patient Engagement," on Monday, April 4th at 4:10 pm. For more information on these breakout sessions, click here.

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Genetic Modification: Science Fact

I am pleased to announce that my article "Genetic Modification: Science Fact" on recent advances in the CRISPR technology has been published in the January 2016 issue of European BioPharmaceutical Review (EBR). To read an electronic version, click here and scroll down the table of content to my article.

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Regenerative Medicine: Tomorrows World

I am pleased to announce that my article "Regenerative Medicine: Tomorrows World" regarding remarkable advances in regenerative medicine has been published in the January 2016 issue of European Biopharmaceutical Review (EBR). To read an electronic version, click here and scroll down the table of content to the last article.

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New Legislation Regarding Pharmaceutical Pricing

The rising cost of healthcare is due to people living longer and the discovery of more advanced technologies. These advanced technologies require longer Research & Development times, much more rigorous regulatory processes and more costly manufacturing processes, resulting in higher costs of drugs. This environment was highlighted when pharmaceutical companies focused on rare diseases and in order to make a favorable return on investments (ROI) on a small population base, pharma/biotech companies had to charge a fair market value (comparison of what it would cost to treat these diseases without these drugs vs. treating with new drugs) in order to recoup their investment and allocate revenue back into R&D.

Drugs for rare diseases such as Gauche Disease or Pompe disease

developed and manufactured by Genzyme, A Sanofi Company, paved the way for this business model. Many companies followed this model including Gilead, which became embroiled in controversy over Sovaldi, a drug used for Hepatitis C. Sovaldi, however, cures Hepatitis C; it is not a chronic treatment and in the long run saves the healthcare system money, as opposed to a chronic treatment, which would cost the healthcare systems for years.

Then greed got in the way with Turig Pharmaceuticals, the sole distributor of Daraprim, a life-saving drug often given to AIDS and cancer patients. The company increased the price for a drug that has been on the market for a long time, from $13.50 to $750 per pill, just months before its founder and former chief executive was charged for running a "Ponzi-like scheme" - allegations he denies as baseless. This one incidence tarnished the reputation of the pharmaceutical industry, which already was being portrayed as the big bad wolf.

Since this Turig Pharmaceuticals controversy over extreme drug pricing was highlighted in the news, there has been public outcry from various organizations, including Congress. In President Obama's 2017 Budget, there are provisions addressing the rapidly rising cost of medications and budget cuts. The provisions buried deep within the budget will cut costs in the following areas:

1. About $140 billion of the spending reductions are tied to proposed changes in Medicare's drug coverage.
2. The budget calls for giving the Health and Human Services secretary authority to negotiate prices for biologic drugs and other expensive medicines, a proposal also made in past years. The government is specifically prohibited from haggling with drugmakers in Medicare's drug benefit program. Another proposal would give HHS broad authority to require drugmakers to disclose information on their costs, such as for R & D.
3. In Medicaid, the state and federal health program for the poor, the budget proposes to limit states' drug costs by allowing them to join together to collectively negotiate with manufactures over payments for high-cost pharmaceuticals.
4. Prohibiting pay-for-delay patent settlements for products going off patent.
5. Encouraging doctors to treat Medicare patients more efficiently and

improve coordination among hospitals and nursing homes, saving $180 billion over a decade.
6. Changes to deductibles and co-pays in Medicare Part B, beginning in 2020, saving $54 billion over a decade
7. Using competitive bidding to set payment rates in the private Medicare Advantage program, saving $77 billion over a decade

For those of us who work in the pharma/biotech/medical device industry, we understand why drugs/devices are expensive because we live and breathe it every day. If you work in the industry, you can skip the statistics on the cost to develop a drug.

On average, the cost to bring a drug to market:

1. It takes 10 - 15 years to bring a drug from research & discovery to approval (market).
2. It costs an average of $2.6 billion dollars with 80% of the total cost spent on clinical trials (Tufts Center for the Study of Drug Development).
3. The overall success rate for clinical trials for a simple compound is the following:

Phase Transition	Success Rate
Phase 1 to Phase 2	63%
Phase 2 to Phase 3	33%
Phase 3 to NDA/BLA	55%
NDA/BLA to approval	80%

The success rate in clinical trials will vary depending on the compound (small molecule vs. large molecule), the indication (primary and secondary), the overall therapeutic area and subcategories within a therapeutic area. The reason the success rate from Phase 2 to Phase 3 is so low is due to a number of reasons, but the main reason is because Phase 2 looks at efficacy with those patients who have the disease, as opposed to safety and tolerability with healthy human beings involved in Phase 1. Since animal studies are not representative of humans, there is no way to predict how those with the disease will respond. Although the Phase 3 success rate is a little higher than Phase 2, when you include more people

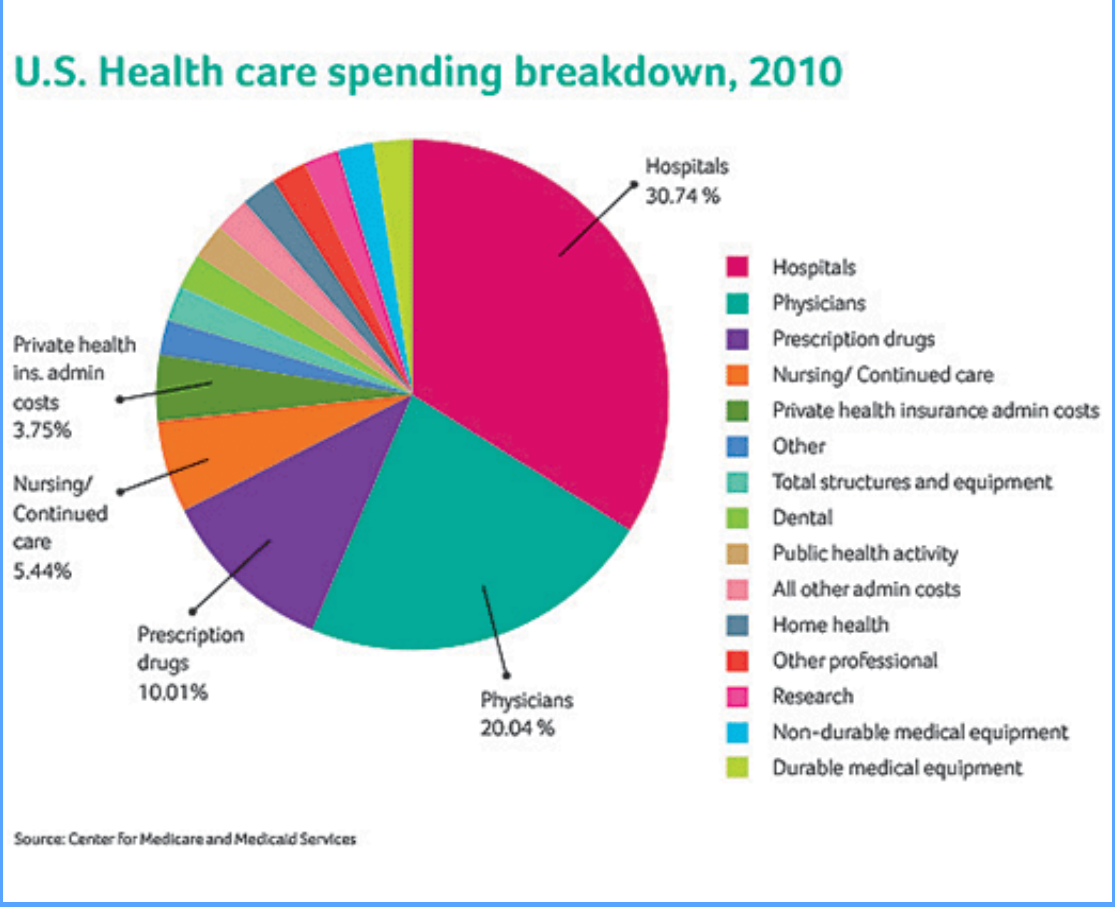
in the study, the pool becomes less homogenous and therefore it becomes unpredictable regarding how people will respond to a medication. All these factors contribute to why it costs so much to bring a drug to market.

Even those in the healthcare (hospitals, physician offices, pharmacy) industry and the lay public don't always understand what it takes to develop a drug through commercialization. All they see is how much they have to pay for the medication at the pharmacy, which is determined by their insurance. The insurance companies determine which drugs they will pay for and how much the patient will have to contribute in terms of co-pays (tier pricing), co-insurance and deductibles. If the insurance company is not willing to cover a drug, then the patient will have to pay the retail price charged by the pharmacy (not the manufacturer) out of pocket.

Since the insurance companies are paying for the drug or reimbursement they have the power to bargain with the manufacturer on price, otherwise the drug will not be on the insurance's formulary and patients have to pay the highest tier copay or not covered at all under their insurance plan and the patient either has to either switch to another drug or pay full retail cost or list price. The full retail cost is not set by the manufacturer, but set by the individual pharmacy.

The whole issue of pricing can get complicated, but what most people don't realize is that the pharmaceutical companies do not set the price in terms of what the patient pays. Manufacturers set the direct manufacturer cost (buying it from the manufacturer directly) but it is the insurance company that determines through bargaining power, how much they will pay the manufacturer and how much they will reimburse the pharmacy if it is covered by insurance. Then the retail price will be determined by everyone who is involved in getting the drug from the manufacturer to the pharmacy, which adds on cost to the price of the drug.

While legislation is creating measures to focus on the drug companies, pricing is not determined by those companies alone. And the cost of prescription drugs in 2010 only represented 10% of the whole healthcare budget.



Health care spending in the United States totaled nearly $2.6 trillion in 2010. Of the total spending, half (51 %) was the cost of medical services provided by hospitals and physicians. Prescription drugs spending accounts for only 10%. While prescription drug costs represent a significant portion of overall health spending, this is one area where there has been slowing in growth spending. From 2009 to 2010, prescription drug costs grew by just 1.2 % while hospital and physician costs grew by 4.9 %.

National Health Expenditures 2014 Highlights

In 2014, U.S. health care spending increased 5.3% following growth of 2.9 % in 2013 to reach $3.0 trillion. This rapid growth experienced in 2014 was primarily due to the major coverage expansions under the Affordable Care Act, particularly for Medicaid and private health insurance. The economy spending devoted to health care expenses was 17.5 %, up from 17.3 % in 2013. In 2014, prescription drugs ($297.7B) still only accounted for 9.9 % of the $3.0 trillion total healthcare spending. From 2010 to 2014, the percentage of prescription drug spending hasn't changed in terms of

overall healthcare spending.

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Closing Thoughts

While congress can set legislation on negotiating drug prices with the manufacturer, it's only one piece of the puzzle. If manufacturers can't make enough money to have an ROI to cover their cost to bring a drug to market (R&D, manufacturing, regulatory, and sales and marketing) and have enough money to support other drug programs, this will definitely slow down innovation. A perfect example is the antibiotic market. The rate of resistance for an antibiotic was shorter than the patent life and with fierce competition and price cutting, the pharmaceutical companies exited the antibiotic market. The government was forced to provide significant incentives for companies to do more research in this area and in the meantime, the healthcare industry is dealing with bacterial resistance such as methicillin-resistant staph aureus (MRSA) and other superbugs that were once restricted to hospitals and are now being found in the community as well.

The price set by the manufacturer is not the price that the patients/consumers pay. So legislation also has to set guidelines for those in the supply chain as well. Insurance companies determine which drugs are covered or not covered and what the patient/consumer pays for those drugs. If the drug is not covered by insurance, or a patient does not have Medicare Part D, then everything is out of pocket and that price is not set by the manufacturer, but by the pharmacy. Legislation must also set guidelines for the insurance companies, just like the federal and state governments tried to set guidelines to curb the rapidly rising costs of healthcare premiums when Obamacare was implemented.

There is no quick fix to this problem and I think we need to look at the

whole picture and all the players involved in order to solve this issue. Currently, all eyes are focusing on only one player, namely the pharmaceutical industry, which is only the beginning of the chain or link and unless we examine the whole system thoroughly, this issue will not be resolved.

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