January 15, 2019

Dear Regina,

Welcome to BioMarketing Insight's monthly newsletter.

Last month, I covered "Nonalcoholic Steatohepatitis (NASH): an Overlooked Disease." If you missed last month's article, click here to read it. This month we'll cover "Conducting the Marketing/Business Due Diligence Early in Product Development Can Avoid Issues and Problems Later in Development and Post Launch."

Read on to learn more about this topic and other current news. The next newsletter will be published on February 15th, 2019.

We encourage you to share this newsletter with your colleagues by using the social media icons below, or by simply forwarding this newsletter or use the link below.

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

Sincerely,
Regina Au
Principal, New Product Planning/
Strategic Plannng Consultant
BioMarketing Insight

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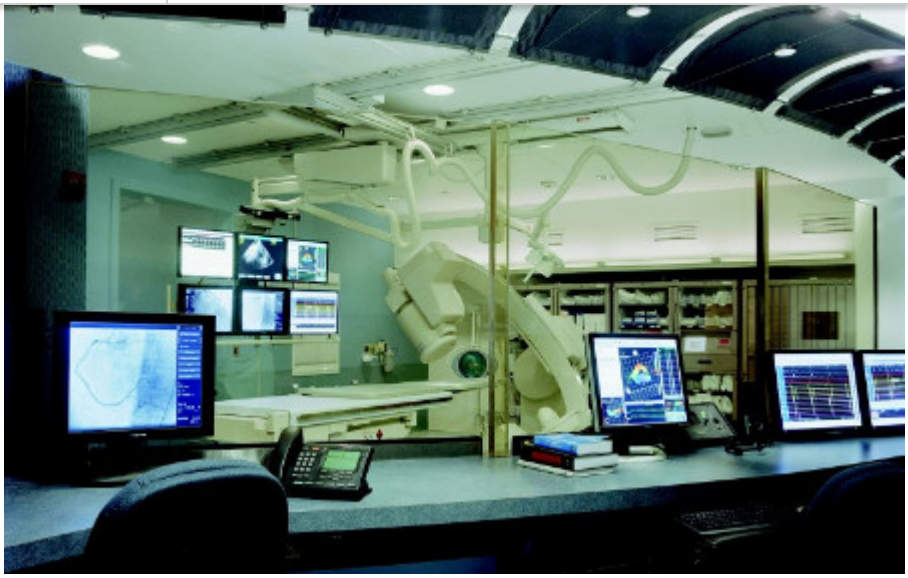

Developing a Product? Commercializing a Product?

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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I am pleased to announce that my article entitled "Updates in Solving the Mystery of Alzheimer's Disease Pathology" was published in the International Journal of Clinical Pharmacology & Pharmacotherapy. This commentary reviews the "Updated Proposed timeline of biomarker abnormalities leading to cognitive impairment" and the involvement of both beta amyloid clearance and plaque, and tau clearance and tau-mediated neuronal injury and dysfunction. To read the article, click here.

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Why Our Microbiome is Important to Our Physiology and Diseases

I am pleased to announce that my article entitled "Why Our Microbiome is Important to Our Physiology and Diseases" was published in the International Journal of Clinical Pharmacology & Pharmacotherapy. This article reviews the results of the Human Microbiome Project and the factors that affect our microbiome in relation to our healthy state and dysbiosis or disease state. To read the article, click here.

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Immunooncology: Can the Right Chimeric Antigen Receptors T-Cell Design Be Made to Cure All Types of Cancers and Will It Be Covered?

I am pleased to announce that my article on "Immunooncology: Can the Right Chimeric Antigen Receptors T-Cell (CAR-T) Design Be Made to Cure All Types of Cancers and Will It Be Covered?" has been published in Journal of Pharmaceutics. This article reviews the mechanism, design and administration of CAR-T cells, and whether payers will pay for this new technology. To read the article, click here.

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Conducting the Marketing/Business Due Diligence Early in Product Development Can Avoid Issues and Problems Later in Development and Post Launch

Introduction:

There must be two key ingredients for a company to be successful: 1) good science; and 2) good business/marketing. We know that if one doesn't have good science, the product won't work. We also know that one needs good marketing to market and sell the product. The controversy is when and how important is it for marketing to be involved in product development.

won't cover it. Marketing due diligence runs parallel to product development to de-risk the process from a business perspective. It also builds commercial value early in product development. Here are the six (6) core reasons why:

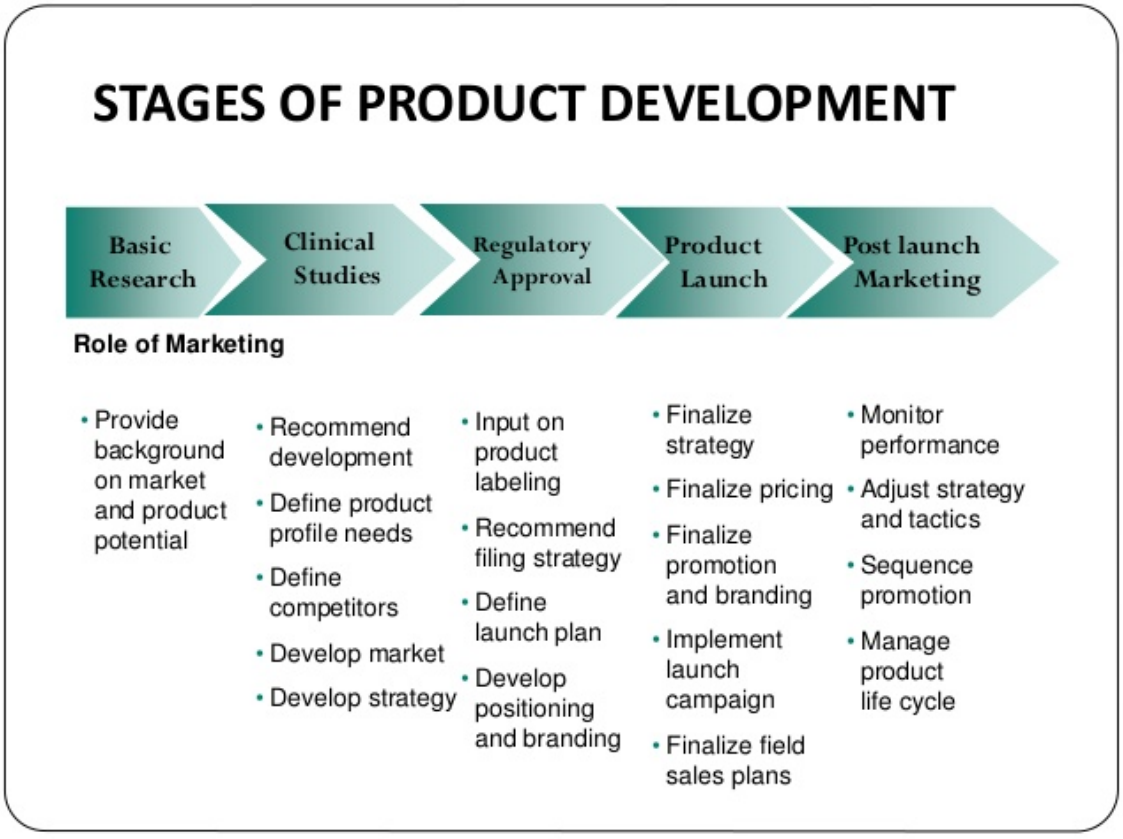


Figure 1: Marketing comes in as early as basic research to provide background on market and product potential.

1) Defining an Unmet Medical Need:

People have always asked me, should I start with the unmet medical need or the technology? My answer is always the unmet medical need. If one knows the problem, one can always find the solution and the technology to solve the problem. If one starts with the technology, then it's a technology looking for a problem, which is very difficult because there is no starting point to a problem.

For example, when nanotechnology was "hot", everything became smaller but there was no commercial application and the technology stalled. For biologics, scientists had the problem of the molecule being too large to get to the right target whereas a small molecule could. So scientists surmised they needed to make the large molecule small by developing a delivery system using nanotechnology to solve the problem and thus, the problem was solved.

unmet medical need is a "critical unmet need" or a "nice to have." Why?

If a person is in pain and goes to see a doctor, the first thing the doctor will ask is where does it hurt and on an Emoji pain scale of one-to-ten (one being no pain and ten being the worse) how would you rate your pain? If the pain is six and below, where there is a smiling face, this is a "nice to have". There may be alternatives in the market to treat their pain or the pain doesn't warrant taking any medication. The patient may say that's nice, but I'm fine with what I am currently using or doesn't need any medication.

If the pain is seven to ten where the patient is crying for the oxycodone or morphine, this is a "critical unmet need." The patient is ready to buy or looking for a drug to relieve his pain. This is where the company will be successful. Marketing conducts this assessment to determine where the unmet need falls within the pain scale.

Marketing determines this by conducting customer interviews in obtaining their opinion on where they perceive is the critical unmet need. It's the customer's need that one is trying to fulfill, not what the company perceives to be an unmet need. It is important that customer interviews be done by an independent marketing firm to eliminate any unconscious bias by the company that can lead the company down the wrong path.

2) Indication prioritization:

Many pharma/biotech companies have a platform technology in hopes that their technology can be used in a number of therapeutic areas. However, just because a molecule is active in one disease, this does not automatically translate to the molecule being active in another disease. This also holds true for marketing: each market or therapeutics area has a different critical unmet need (if any), different market and technology trends, different competitors, etc.

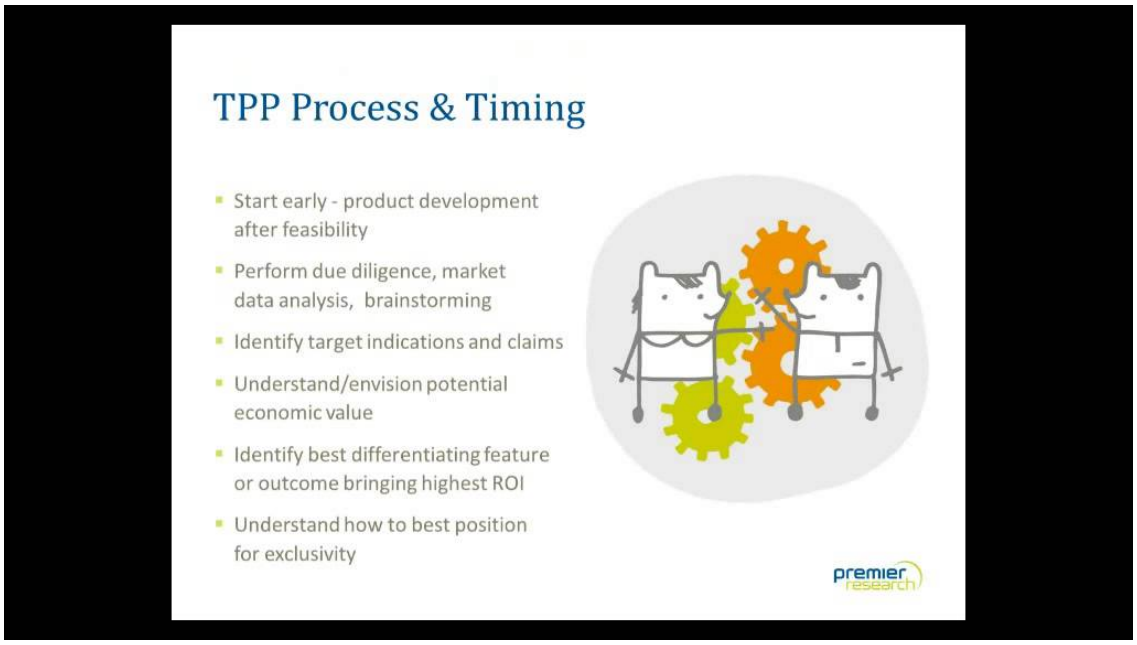
In conducting the marketing due diligence, a company can narrow down ten (10) different potential therapeutic areas to the top three areas with the best market potential based on the attributes of the product. A typical company can't afford to work on 10 areas at the same time due to budget restraints. This also avoids spending time and money only to discover that the market is not large enough to meet the company's goals, the customer won't buy it, or insurance won't pay for it because they don't see the advantage of using the drug that is generally more expensive.

3) Determining market potential:

There are two important components:
a) Where is the critical unmet need in the standard treatment regiment? Is it first line, second line, or third line therapy? An unmet need in first line therapy has more market

smaller and smaller; and

b) How many people have the same definition as the hypothesized critical unmet need? The market potential should be the middle of the distribution curve, more than 70% of the population. One can have a critical unmet need but if only 500 people share this view, this is not a big enough market.



4) Target Product Profile = Commercial Profile:

Once a company chooses its lead candidate where the molecule demonstrates activity, the company continues to develop it further to a Target Product Profile (TPP) or commercial profile that the company will file with the FDA, conduct clinical trials and market to the public.

R&D and Marketing are involved in developing the TPP. R&D will develop the dosing and stability, efficacy, and minimize side effects. Marketing will set the goals or specifications based on what the market dictates and the product has to be better because why would a customer buy a product if it's not better?

If marketing doesn't set the TPP, R&D could develop the product and be satisfied with a product that is once-a-day with 90% efficacy. However, what if the other products already on the market are a once-a-week product with an 85% efficacy rate? One could say the company with the 90% efficacy is a better product. Yet, marketers know that patient compliance, taking their medication is a huge issue. Compliance goes down to 50% with a once-a-day product after the first year maximum two years.

A drug could have a 100% efficacy, but if the patient is not taking the medication, the drug

but it must be done in order for the product to be successful.

Because patient compliance is so important, companies have strived for dosing that achieves once/month, once/every six months and soon once/year. However, there is always a trade off to drugs that last longer in our system so it can be dosed once-a-week. The concerned is how will this affect the side effect profile? Or if the patient misses a dose or takes too much, how will this affect the efficacy and side effect profile? This is one of the reasons why drug development is long and expensive.

Other characteristics of the product that may affect patient compliance are the size, shape, color, type of coating of the pill or an injection. It is crucial to understand the needs of the patient in addition to what the market dictates with competitors.

5) Product Adoption from All Seven (7) Stakeholders:

The 7 stakeholders or 7 Ps are; 1) Patient; 2) Physician; 3) other healthcare Professionals ; 4) Policy or regulatory; 5) Payer- insurance companies, government; 6) Politics or legislation; and 7) Patient advocacy groups.

Each stakeholder has different needs or requirements that must be satisfied to achieve product adoption because they will influence whether a product will be available (market access) to the patient when the physician prescribes the product. These needs also influences the TPP of a product. For example:

a) Policy:
The expectation or bar for regulatory approval has gotten higher. There are no longer clinical trials compared to placebo except in rare circumstances but compared to the standard of care or a similar medication already on the market. The expectation is for the company's product to be equal or better than the existing product. A company could get FDA approval as being equally effective, but this would classify the product as a "nice to have" with no advantage over the currently marketed product. Defining the TPP to be better solves this issue.

b) Payer:
The expectations for reimbursement are even higher. Payers expect a product to be better if they are going to pay for a new product that is generally more expensive. What is the value of the product that warrants more money?

The product also has to demonstrate that the drug will save the healthcare system money both short-term and long-term. If payers are going to spend money, they want to know they are spending less today than what they would have spent if the patient was not on the drug in future years. Or if they are spending more money today, they won't be paying for

To obtain this data, one needs to build it into the company's clinical trial design with Phase 1 trials. When one files an IND (Investigational New Drug), the clinical trial design is included and if one does not include it in Phase 1, one may forget to include it in the Phase 2 and 3 trials. It's better to plan for it, then modify it similar to an adaptive clinical trial.

6) Avoid Issues and Problems Later in Development and Post Launch:

The advantages of doing the marketing due diligence early is that once one files an IND, everything becomes public. Before IND, one can make mistakes or change one's mind and no one will ever know except for the people in the company.

The farther one goes down the product development process and discovers the indication is not correct or that the market potential is significantly lower than expected, one has to decide, does one go back and develop the product further or does one continue down the path knowing that the expectations will be lower.

Going back once into Phase 2 or 3 to correct the situation can be very expensive since eighty percent (80%) of the R&D budget is allocated to the clinical trials.

This is a very difficult decision to make. If one decides to go back, that means more money and time is required resulting in time delays, possible missing milestones and management and investors will not be happy.

If one decides to move forward knowing that sales maybe significant lower than forecast, management will not be happy since sales have already been allocated to their 5 and 10 year plans. There is nothing worse than to discover that sales projections are high but the actual sales are low or flat because the due diligence was not conducted early in product development.

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Closing Thoughts

It is very important from a business perspective to conduct the marketing due diligence as early as basic research to avoid the issues just described. It is never too early to do the due diligence, but it can be too late to fix it in R&D resulting in a poor return on investment (ROI). This doesn't mean that unexpected things can't happen, but at least one has de-risked the process to the best of one's ability.

Sometimes it may appear that conducting the marketing due diligence may seem easy and it would be tempting to do it oneself. However, one wouldn't want a chemist to do biology work or visa versa. Hire an expert or consultant if this is not one's area of expertise. A penny saved can turn into millions of dollars flying out the window.

For questions or need to conduct marketing due diligence, please email me at regina@biomarketinginsight.com or call me at 1-781-935-1462.

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Should you have any questions or need of assistance with your business due diligence, determining your product's value proposition and economic value of your product, feel free to contact me at 781-935-1462 or regina@biomarketinginsight.com.


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