Summer Training at

(April 4 – June 4, 2014)

Analog Analysis for Launch Trajectory

By
Smita Kadam

Under the guidance of
Dr. Sandeep Narula

MBA-Pharmaceutical Management (MBA-PM)
2013-2015

The IIHMR University, Jaipur
2014

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CERTIFICATE

This is to certify that **Ms. Smita Kadam** student of Institute of Health Management Research University; Jaipur has undergone summer training at **IMS Health, Gurgaon** from April 07, 2014 to June 06, 2014.

The candidate has successfully carried out the project **"Analog Study for Launch Trajectory"** assigned to her during summer training & her approach to study has been sincere, scientific & analytical.

This summer training is a partial fulfillment of the course requirements.

We wish her success in all future endeavors.

Col. (Dr.) Ashok Kaushik
Dean Academics & Student Affairs
IIHMR University, Jaipur

Dr. Sandeep Narula
Associate Professor
IIHMR University, Jaipur

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TO WHOMSOEVER IT MAY CONCERN

This is to certify that **Ms. Smita Kadam** has successfully completed her internship at **IMS Health India Private Limited.**

The tenure of her internship was from **7th April 2014 to 6th June 2014**.

During her tenure in IMS Health she has worked on live/internal projects and has also actively participated in all extracurricular activities.

It was a pleasure having her with us and we wish her all the very best for her future endeavors.

Thanks and Regards

(Human Resource)

(Smita Kadam)

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To Whom So Ever it May Concern

This is to certify that **Ms. Smita Kadam**, a student of the Post Graduate Diploma in Pharmaceutical Management, IIHMR Jaipur has worked under our guidance and supervision. This Summer Project Report on **'Analog Study for Launch Trajectory'** has the requisite standard and to the best of our knowledge no part of it has been reproduced from any other summer project, monograph, report or book.

Ms. Priyanka Chachra
(Associate Consultant,
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This is to certify that **Ms. Smita Kadam**, a student of IIHMR, Jaipur has worked under our guidance and supervision. During her tenure in **IMS Health** from 7th April to 6th June 2014, she has worked on the following projects:

1. Rheumatoid Arthritis:
   a) Epidemiology Review of Literature on Rheumatoid Arthritis(Japan, Brazil, EU, USA)
   b) Economic Impact, Biologic Treatment, Biosimilars in Treatment of Rheumatoid Arthritis in (Japan, Brazil, EU, USA)
2. Analogue Study for Launch Trajectory
3. Middle East Pain Market Assessment
4. Epidemiology & Pipeline Assessment Soft-Tissue Sarcoma
5. Physician Social Media in Japan
6. Country Landscape For Pakistan & Iraq

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Date:
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I hope that I can build upon the experience and knowledge that I have gained and make a valuable contribution towards the industry in coming future.

INTRODUCTON

Company Profile:

IMS Health founded in 1954 is the world's leading information, services and Technology Company dedicated to making healthcare perform better.

The company connects more than 10 petabytes of complex healthcare data on diseases, treatments, costs and outcomes to enable the clients to run their operations more efficiently.

Draws on information from 100,000 suppliers and on insights from more than 45+ billion healthcare transactions that are processed annually. Operating in 100+ countries IMS Health has approximately 10,000 professionals who drive results for over 5,000 healthcare clients globally.

Customers include pharmaceutical, medical device and consumer health manufacturers and distributors, providers, payers, government agencies, policymakers, researchers and the financial communities.

Corporate Social Responsibility

At IMS Health, responsibility begins with commitment to customers. It's a commitment to doing all to advance the quality of global healthcare.

They also inspire their teams to behave responsibly, ethically and always with an awareness of the greater good. They extend that support to our communities, where IMS Health makes a lasting contribution to a range of cause-related projects, philanthropic and fundraising activities.[1]

Background of the Project:

Launch is one of the most critical moments in a product life cycle. For 85% of Pharmaceutical launches, the product trajectory is set in first six months. Until recently companies were not required to make adjustments to their launch plans. But the world has changed, launches have become more numerous, smaller and more competitive as the health care environment has become much more dynamic and diverse. [2]

Product penetration into the market depends on the characteristics of the market, market dynamics and product attributes and also the promotional efforts required. [3]

The project aims to narrow the list of potential analogs to determine the required levels of promotional investments and to better understand how to grow a brand after the initial 6 month launch phase.

The pharmaceutical giant X expects to launch Drug A for obesity in 2015. The Company X wants to determine the required levels of promotional investments and understand how brands are able to significantly improve their trajectory 6 months after launch.

The methodology for the same proposed by IMS Health was ‘’An Analog Study’’
The total Analogs with the High Sales in US were selected out of these total Analogs 15 were selected from the market based on the attributes of the Drug A i.e. the analogs used in Chronic Indications, Physician Familiarity, injectible formulation and Label expansion.

Out of the 15 Analogs 5 were selected for further deep drive case study these 5 analogs were the ones with the increase in the sales and new-to-brand prescription volumes.

The 5 Analogs were further studied to understand the Promotional activities they had gone through for the improved Launch Trajectory.

The study concluded that the Promotional activities such as Co-pay Programmes & DTC activities were responsible for the improved Launch Trajectories.

SCOPE OF STUDY

The project aims to profile brands that developed new or underserved markets and determine the required levels of promotional investment; and to better understand how to grow a brand after the initial 6 month launch phase.

Managerial Scope of Study:

The study helps to understand different marketing strategies involved after the launch in different market situations.

REVIEW OF LITERATURE

The Pharmaceutical industry has witnessed rapid changes in the environment for new launches in the last decade. This has now made the launch activities vital for the giants in the industry to make their mark in the market. [4]

Product launch signifies the point at which consumers first have access to a new product. It is a debut of a product into the market. A product undergoes pre launch activities before the launch and post launch activities after the launch.

Today's best marketers recognize the need for a more complex approach that goes beyond traditional marketing concept.

Drug Analogs are the Analogs of an existing drug molecule that share similarities with the original compound. [5] These similarities could be structural, functional or regarding the same market characteristics, indications, target segment etc.

In this project the drug analogs refer to the drugs that are prescription drugs and the drugs with the close market characteristics, target segment to the original drug.

Co Pay Assistance Co payments are where policy holders pay a specific dollar amount per prescription. In the United States, overall drug spending in the private sector rose by 15-20

percent per year during the 1990s. In 2002 alone, national spending on prescription drugs exceeded $160 billion. Because of these increased costs, some employers and insurers have redesigned the health insurance plans to allow for greater sharing of costs with consumers. In particular, they have started insurance systems with flat co-payments (where policy holders pay a specific dollar amount per prescription) to systems of coinsurance (where policy holders pay a fixed percentage of the total prescription price). [6]

Studies have shown that greater cost sharing reduces consumer spending on prescription drugs and therefore lowers employer costs. Others have argued that this trend does not undermine overall health, since patients facing rising costs will reduce consumption of nonessential medications more than consumption of vital chronic care drugs. [6]

DTC Direct to consumer pharmaceutical advertising (DTCPA) has grown rapidly during the last decades. It is an effort by the pharmaceutical companies to reach the patients directly by the use of popular media. The U.S and New Zealand are the only countries that allow DTCPA that includes product claim.

The types of DTC are:

- Help-seeking ad - It provides only information about a medical condition and encourages patients to contact their physician but doesn't mention a product.
- Reminder ad- It includes the product name; this type provides information about strength, dosage form, or price, but it doesn't mention the indication or make any claims.
- Product claim ad – This type mentions the product and its indication and includes efficacy or safety claims.

Each category of ads is subject to different FDA regulatory restrictions. [7]

Secondary Data Research/Meta Analysis is the data not collected by the researcher directly from the subjects. It may have been collected from:

- Journal articles, Conference proceedings

- Organizations Grey material e.g. sales figures, information about product launches etc published by the organization
- Academic, media, professional bodies set up for collecting data directly from government or international bodies. [8]

In 2012 Danzon *et.al.* Studied the effect of regulation on Drug Launch and pricing in Interdependent Markets and concluded that launch timing and prices of new drugs are related to a country's average prices of established products in a class. Thus to the extent that price regulation reduces price levels, such regulation directly contributes to launch delay in the regulating country. Low-price countries also have indirect effects, contributing to launch delay and higher launch prices. [9]

In 2013 Kornfield *et.al.* Did a study on the Promotion of prescription drugs to consumers and providers from 2001-2010 and found that Pharmaceutical firms have began heavily promoting their products and have changed marketing strategies due to reductions in new product approvals, restrictions on some forms of promotion, and the expanding role of biologic therapies. They further concluded that Spending on meetings and electronic promotion have increased, yet these channels account for a small fraction of promotion. Despite its growth in the first half of the decade, DTCA also represents a minority of promotion and is driven by television advertising. [10]

In 2011 Duflos *et.al.* Studied the impact of changes in market structure on US drug pricing, marketing and utilization the inference of the study was that the demand for prescription drugs should be inversely related to drug prices and directly related to marketing expenditure. Changes in market structure due to patent expiration or other factors is likely to reduce both the average price of a drug and marketing expenditure, they used longitudinal, molecule-level data virtually on all prescription drugs sold during the period 2000–2004 to analyze the impact of changes in market structure (primarily resulting from patent expiration) on U.S. drug prices, marketing, and utilization. Price and marketing expenditure both declined by about 50–60% in the years immediately following generic entry, but the number of prescriptions remains essentially constant during those years. The two effects of increased competition on drug utilization –

positive (via price), and negative (via marketing) –so the net effect of patent expiration on drug utilization is zero. [11]

In 2011 Lee *et.al.* Compared the product launch between the developed and the emerging markets and concluded that customer education and promotion discount pricing strategy enhance new product performance for both the Taiwan and U.S. market. However, there are some cross-national differences. Emotional advertising strategy is generally appreciated in the U.S. market but not in the Taiwan market. [12]

RESEARCH QUESTION

- What are the marketing activities responsible for change in Launch Trajectory of Analogs, after 6 months?

HYPOTHESIS

H_0 Hypothesis: The post launch marketing activities of the drug/Analogs can be responsible for the successful launch trajectory.

STUDY OBJECTIVE

The main objective to conduct this research is to identify the marketing activities that can be responsible for the change in trajectory of Analogs, post launch.

Primary Objective:

- To identify analogs with high sales & improved trajectories post launch
- To identify the marketing activities that can improve the launch trajectories of analogs, post launch

METHODOLOGY

1. **STUDY AREA**: United States
2. **STUDY DESIGN**: Qualitative & Quantitative/Secondary Data

DESIGN TOOL:

1. **SAMPLE SIZE**: 15 Drug Analogs were selected.

INCLUSION AND EXCLUSION CRITERIA:

Inclusion criteria: The Analogs in the market that closely mimic the attributes of the Drug A.

Exclusion Criteria: The Analogs in the market that do not mimic the attributes of the Drug A.

2. DATA COLLECTION:

Data was collected using IMS Internal database and secondary desk research.

3. Analog Analysis:

The drugs with High Sales in US were first selected. Thereafter to select the analogs closely similar to the attributes of Drug A, the attributes of the Drug A were studied.

1) Study the attributes of Drug A

Attribute analysis of Drug A:

SWOT ANALYSIS:

STRENGTHS	WEAKNESS
1. Market size and growth rate ~20.7% 2. Drug Familiarity with the physicians 3. Chronic Indication	1. Concerns around cost
OPPORTUNITIES	**THREATS**
1. Target the niche market 2. Label expansion	1. Obesity market has had a history of failed drugs 2. Patient inconvenience as the drug is an injectible

The attributes/characteristics matching criteria for the Analogs were:

- Chronic Indication
- Injectible
- Life style product/surgical alternative
- First to market/Established leader in the market
- Generics/OTC in the market
- Market size

2) **Analog Selection:** Based on Drug A's attributes/matching criteria's 15 analogs were selected

3) **Further Study of the selected 15 Drug(Analogs)**

The selected Drugs (Analogs) were further studied to understand:

- Increased Sales after 6 months
- Trajectories after 6 months

4) 5 of the 15 Analogs were identified with the improved Launch Trajectories as they had increased
    - Sales
    - Changes in new-to-brand prescription volume

And were selected for the further study to understand:

Integrated Marketing methods observed for the change in their trajectories.

Promotional & marketing events:

- Journal publications
- Conferences & meetings
- Direct to consumer(Advertising) spending
- Retail value of the sample

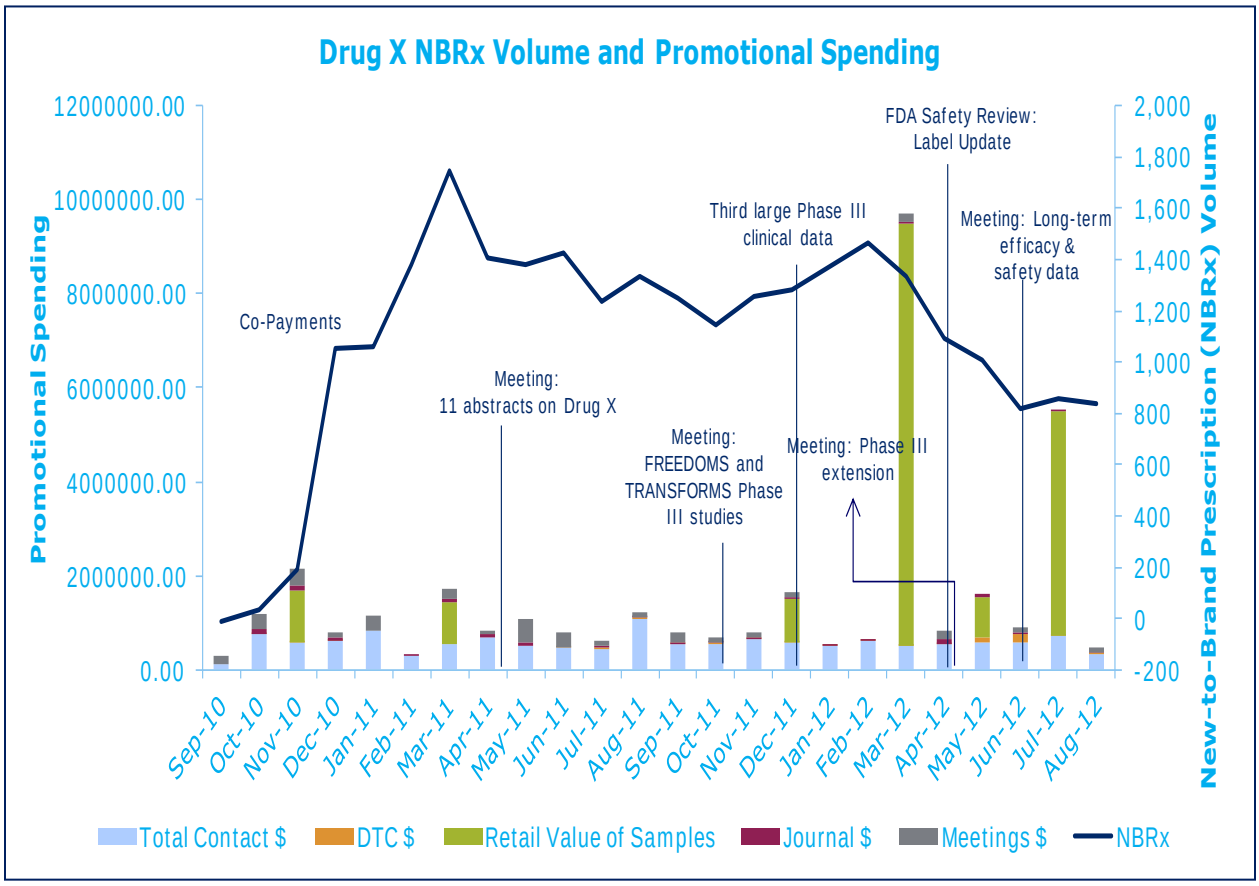
The secondary desk research was also carried out for the 5 Analogs to understand the reasons for the increase and decrease in the prescription volume.

ETHICAL CONSIDERATION

- The confidentiality of the company's identity and Data was ensured.
- The Data collected was authentic and reliable.

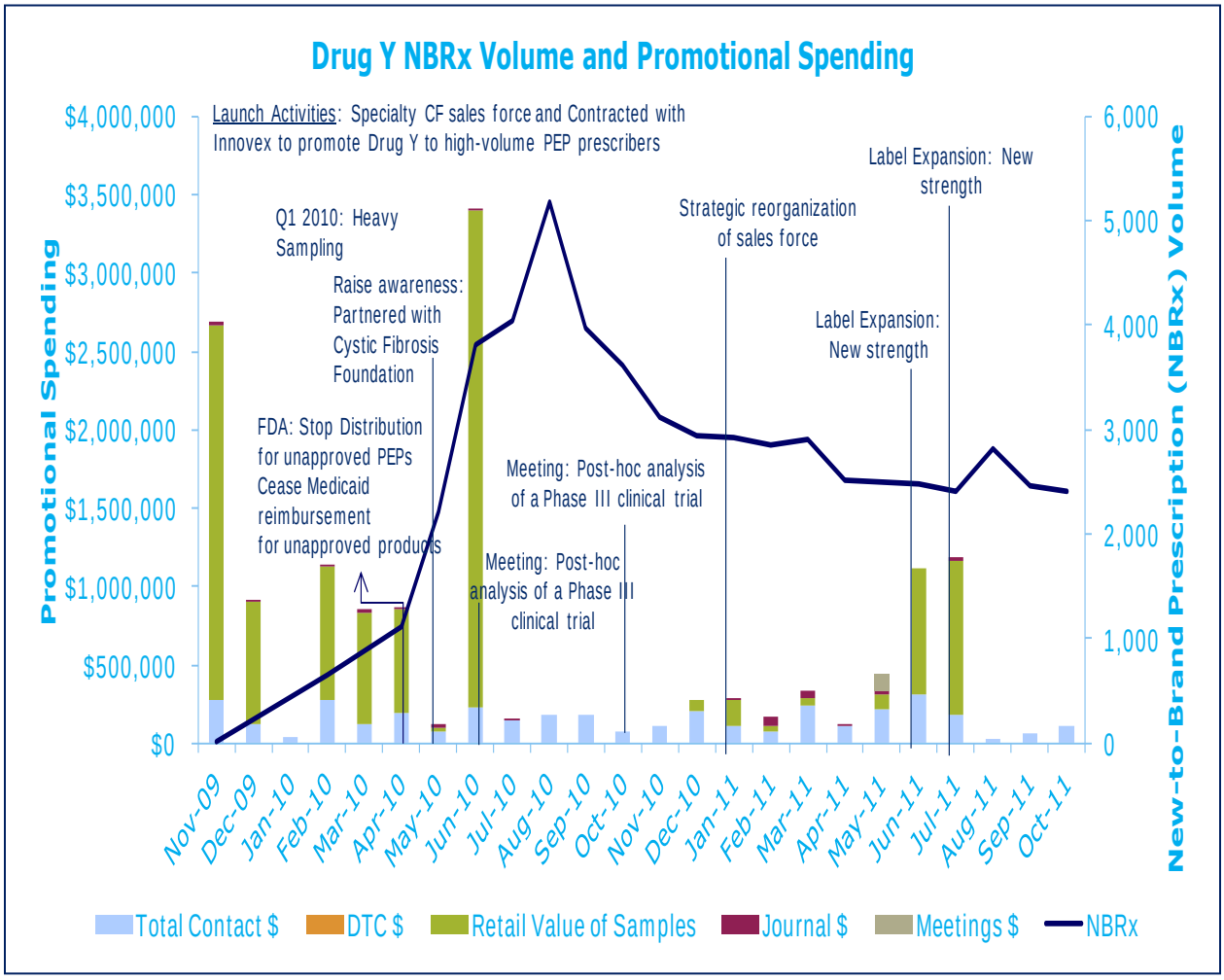
RESULTS

<u>Analog1:</u> Drug X trajectory coincides with Co-Pay Program



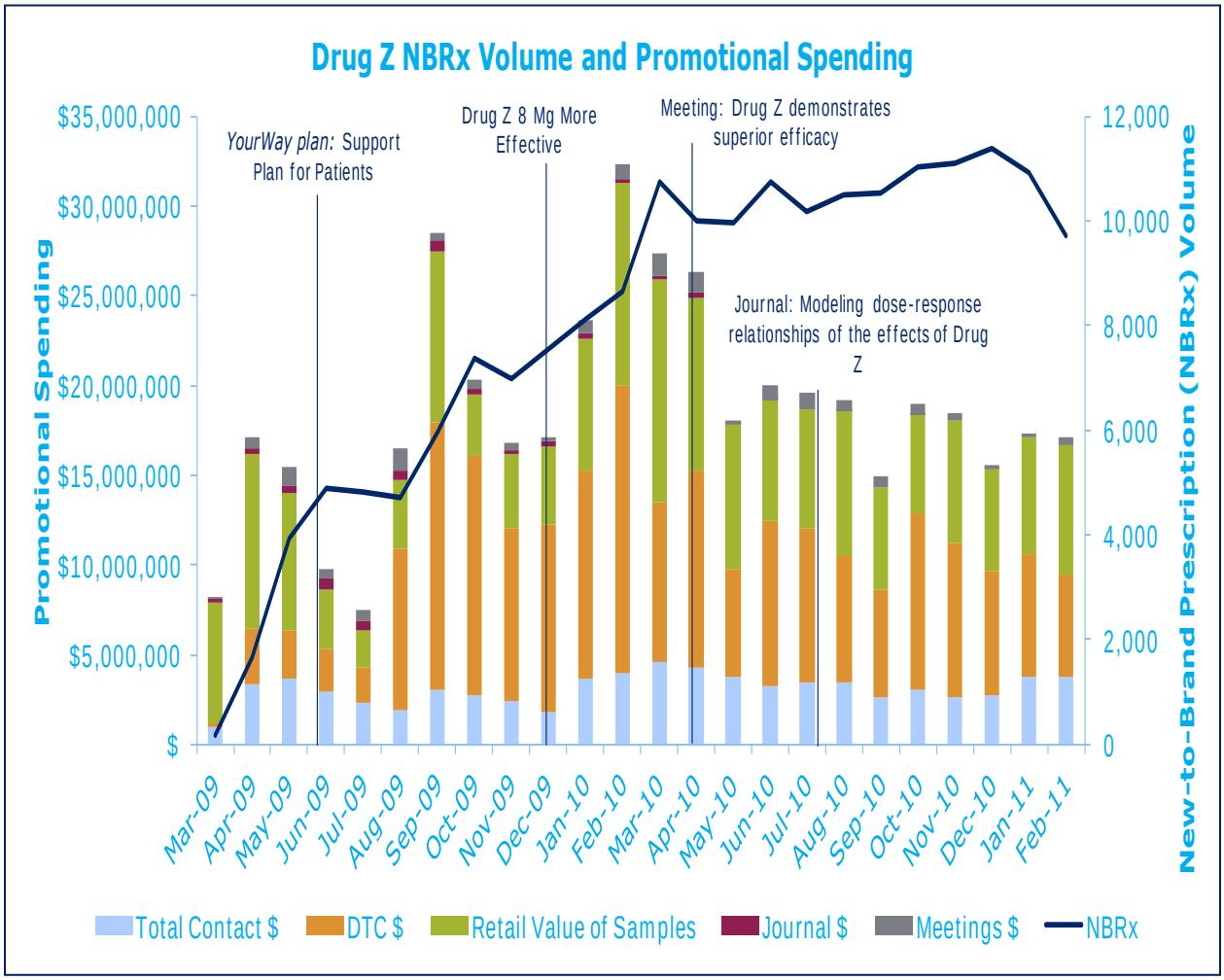
Interpretation: The launch path has increased with the Co-payments program, the other aggressive marketing activities include Continuous Medical Education (Meetings)to doctors at regular intervals, Total Medical Representatives visits (Total Contacts), Journal publications and Drug Samples to doctors (Retail Value of Samples).

Analog 2: Drug Y trajectory coincides with Ban of Competitive Drugs



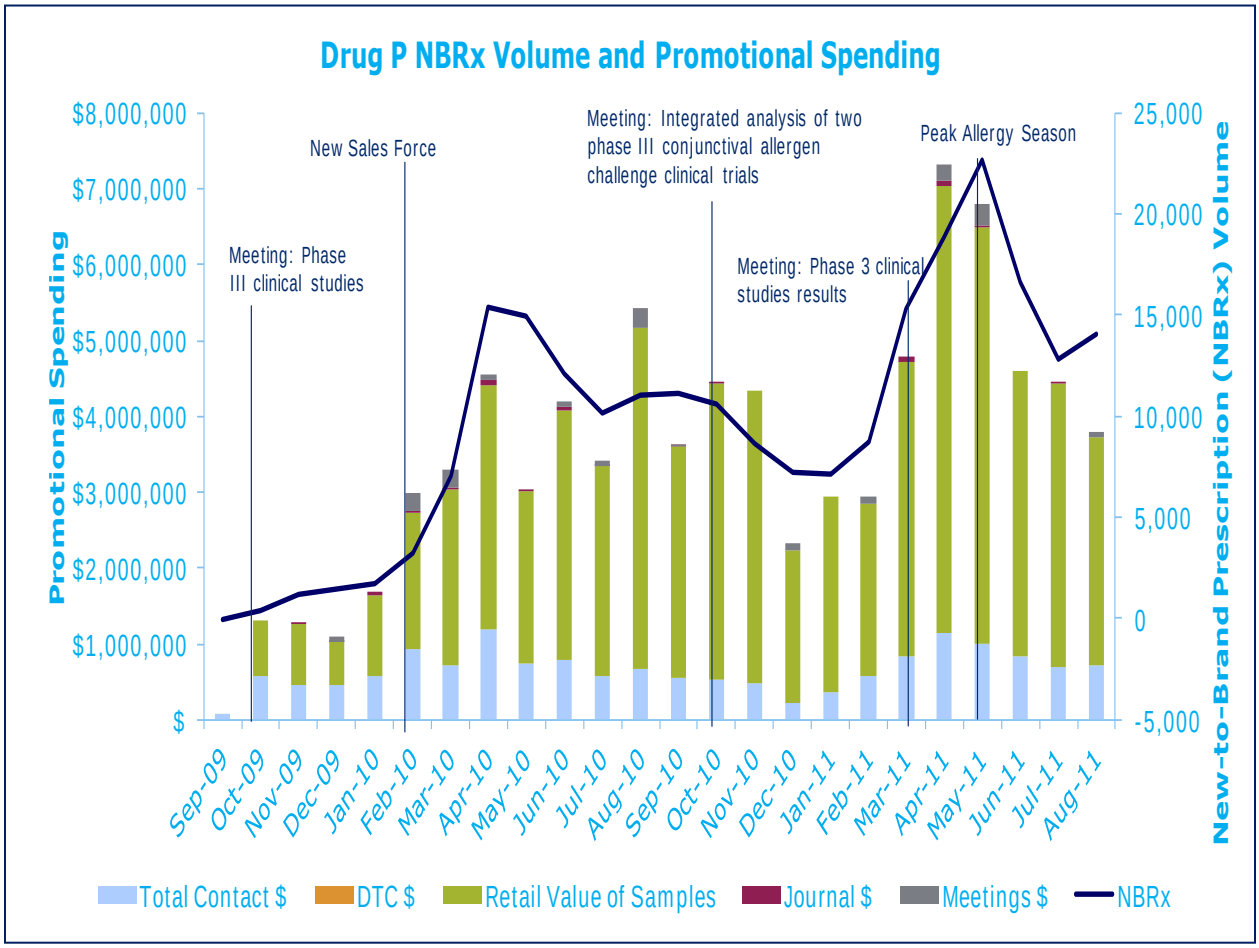
Interpretation: The launch path has increased with the Ban of the competitive drugs, the other aggressive marketing activities include, Total Medical Representatives visits (Total Contacts) and large volume of Drug Samples to doctors (Retail Value of Samples).

Analog 3: Drug Z trajectory coincides with DTC



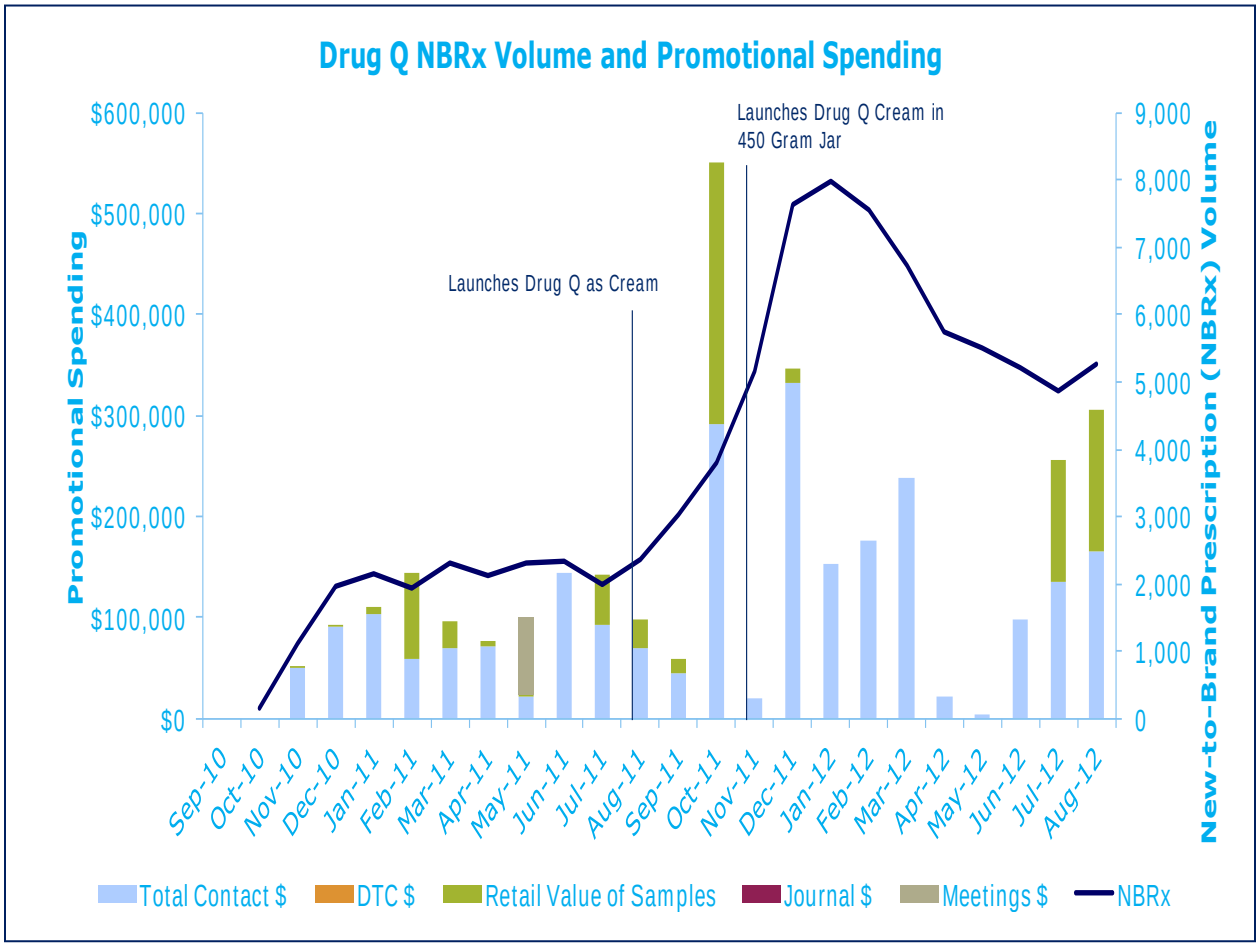
Interpretation: The launch path has increased with the Direct to Consumer Advertising (DTC), the other aggressive marketing activities include Total Medical Representatives visits (Total Contacts) and Drug Samples to doctors (Retail Value of Samples).

Analog 4: Drug P trajectory coincides with Allergy Season



Interpretation: The launch path has increased with the Allergy Season, the other aggressive marketing activities include Continuous Medical Education (Meetings)to doctors at regular intervals, Total Medical Representatives visits (Total Contacts) and Drug Samples to doctors (Retail Value of Samples).

<u>Analog 5:</u> Drug Q trajectory coincides with Label Expansion



Interpretation: The launch path has increased with the Label Expansion, the other aggressive marketing activities include Continuous Medical Education (Meetings)to doctors only in the month of May 2011, Medical Representatives visits (Total Contacts), Journal publications and Drug Samples to doctors (Retail Value of Samples).

CONCLUSION

Thus, we can conclude that the post launch marketing activities such as **Co-pay Programs, DTC (Advertising), Label expansion,** Continuous Medical Education (**Meetings**) to doctors at regular intervals, Total Medical Representatives visits (**Total Contacts**), **Journal publications** and Drug Samples to doctors (**Retail Value of Samples**) can be the reasons **for the improved launch trajectories of the Drug (Analogs).**

Thus we can accept the H_0 Hypothesis that the post launch marketing activities of the drug/analogs can be responsible for their successful launch trajectories.

The Pharmaceutical Giant X can use any of the above mentioned post launch marketing activities as per their convenience for their new Drug A.

DISSCUSSION

Due to increasing competitive pressures, many believe the launch of new blockbuster drugs will no longer provide the double-digit revenue growth experienced in previous decades. Instead, pharmaceutical companies will need to look outside the box and expand their portfolios - not just with smaller products, but with drug-device combinations, biological and genetic based products.

Product Managers will have to evaluate and address the gaps in existing product launch processes to achieve peak performance in future product launches. They will have to come up with innovative and flexible launch strategies that can be altered, monitored and executed easily and effectively.

If R&D productivity increases are realized, the trend of large number of product launches in new or niche markets will continue.

The trend of reimbursement models or Co-pay Programmes and DTC are on increase in US.

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