CASH COW VERSUS ONE-HIT WONDER: ANALYSIS OF MANAGEMENT'S PREFERENCE FOR SMOOTH ACCOUNTING ON PHARMACEUTICAL INNOVATION

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Abstract - Prescription medications account for 10% of the healthcare expenditure in the United States. However, there continues to be a shortage of innovative pharmaceutical products. In economic business models, companies, stake holders and markets prefer products with a steady revenue stream. In this paper, we evaluated the influence of preference for a steady stream of revenues by comparing the net present revenues of chronic, long term pharmaceutical products and curative, short term pharmaceutical products.The results suggest that curative products offer better net present values to pharmaceutical manufacturers and to health insurance payers, but its non-smooth temporal revenue profile is not preferred by markets and causes budgeting problems to health insurance payers.

Index Terms - Biotechnology, Innovation, Management, Pharmacy.

I. INTRODUCTION

Healthcare expenditure in the United States has exceeded 3.2 trillion dollars annually in 2015, accounting for 17.8% of its gross domestic product. 10% of the healthcare expenditure is on prescription drugs [1]. One of the drivers for the rising cost is the increasingly high cost pharmaceutical development: the overall cost of developing a new drug exceeds $2.8 billion dollars [2][3].Further, failures are a necessary component of drug development process [4].

However, even with the increasing spending on pharmaceutical development and consumption, there is still a shortage of innovative pharmaceutical products. Many reasons for this shortage have been suggested, such as industry's relocating funding from research and development to marketing [5].

In this paper, we examine another factor that can contribute to the lack of pharmaceutical products that provide medical breakthrough: the temporal profile of a pharmaceuticals' revenue to its manufacturer and payment by health insurance payers. Specifically, we hypothesize that the preference for smooth earnings profiles play a role in both a pharmaceutical company's decision to develop a product and an insurance payer's decision to reimburse a product, discouraging the development of curative products.

Financial valuation is important for the success of a business. To help investors and shareholders have a good valuation of a company, companies conventionally like to have a steady stream of cash flow. It is extensively documented in the accounting literature that, in general, markets and company stakeholders prefer monotonically increasing earnings that are characterized by smoothness [6].To cater to this preference, a company's managers would take various measures to modify its temporal earnings profile to demonstrate smoothly increasing earnings [6]. Cash cow refers to a product that provides a steady stream of revenue, while one hit wonder refers to a product that has a sharp peak in sales but does not provide a long term steady stream of revenue.

One of the obstacles discouraging pharmaceuticals companies from developing curative or preventive pharmaceuticals is this preference. Since markets reward, and management prefers, a steady stream of income, drugs that manage chronic medication conditions are more desirable than curative drugs because they generate long run, consistent earnings and cash flows. Drugs that create curative effects, while innovative and clinically superior, don't generate consistent earnings and cash flows.

Further, from the perspective of health insurance payers, the preference for smooth earnings also discourage the reimbursement of curative products. Health insurance payer's earnings is revenue minus expense. A curative product would cause an unevenness in the expense of a health insurance payer.

In this paper, we examine this issue by the following steps: (1) we analyze the empirical data of revenues of chronic medications and case example of curative hepatitis C products to understand the effect of the preference for smooth earnings; (2) we examine empirical evidence that the markets prefer pharmaceutical products of smooth earnings potential; (3) we develop an analytical model of a health insurance payer's expense with curative products; (4) we propose a solution to this problem.

II. METHODS

We selected 12 public pharmaceutical companies based in the United States based on their market capitalization. We use each company's Notes to the Financial Statement (10-K) published on the SEC's EDGAR website for our data.[7] Data of 95 pharmaceuticals that provide chronic management of chronic medical conditions were found in the financial statements. Patent year is as that projected on each company's financial statement from the time of drug

approval.

To find the total revenue a chronic drug would receive over its lifetime that would be valued at the beginning (i.e., FDA approval), the Discounted Total Revenue for a chronic pharmaceutical is calculated as:

$$\text{Value} = \sum_{t=1}^{t=N} \frac{CF}{(1+r)^t}$$

, where t = year, from year 1 to year N. N is the number of years between FDA approval and patent expiration. For simplicity, we assume the cash flow after patent expiration to be negligible due to completion from generic drugs and time discount.

CF = cash flow each year, which is the mean total drug sales revenue of a drug in a year. For simplicity, it is assumed to be constant.

r = discount rate

In this discounted cash flow model, the three variables that change the net present value are: mean cash flow each year (CF), number of years between the FDA approval and patent expiration (N), and discount rate (r). We assume cash flow the same as revenue for simplicity.

III. RESULTS

A. Research Question 1.Do chronic pharmaceuticals provide more net present revenue than curative pharmaceuticals? If not, then the financial risk of developing curative pharmaceutical products is not due to lower net present revenue.

To understand the number of years to use in the net present revenue model, we first analyzed the number of years between the FDA approval and patent expiration. With 41 brand name pharmaceuticals examined, the median number of years between the FDA approval and its projected patent expiration is 13 years and the mean is 12.7 years.

Then, we examined the average annual sales of chronic pharmaceuticals, which is shown in Table 1. This represents an optimistic overestimate as only the drugs that produce the most revenues are reported in a company's Notes to Financial Statement (10-K). The average is $1.072 billion dollars per year, while the median is $694 million dollars a year. The difference between the mean and the median is consistent with the ideas of "blockbuster" drugs: most of the drugs have sales less than $1 billion dollars a year, but a small number of "blockbuster" drugs have sales more than $1 billion dollars each year. The distribution is shown in Table 1.

Meanwhile, the net present revenue of Harvoni is at least 30 billion dollars, in a conservative estimate. How much does the mean annual revenue of a chronic pharmaceutical need to be to have 30 billion dollars of revenue, given that the patent exclusivity lasts for an average of 13 years? The analysis is displayed in Table 1. The annual revenue of a chronic pharmaceutical needs to be 3 billion dollars to have a net present revenue of 30 billion dollars.

In Summary of Research Question 1, the discounted revenue analysis shows that a curative hepatitis C product's net present revenue is comparable with that of the chronic pharmaceuticals that have an average of more than 3 billion dollars of revenue a year. This eliminates the risk that a curative product does not provide enough revenue to adequately cover cost and provide an adequate return on investment. This is due to several seasons. First, discount rate: the cash received in the future is not as cash received today. Second, patent expiration: after an average of 13 years, a chronic pharmaceutical loses patent exclusivity. When the patent expires, the sales plummet, because generic versions of the product are being sold. Third, competition: even before patent expiration, during the 13 years, a new drug can enter the market and take away market shares.

When a company develop develops a new product, the main risks include the risk of not generating enough revenues and the risk of non-smooth earnings. As the risk of not generating enough revenues is eliminated, the next risk that managers, stakeholders, and markets would like to avoid with curative products is the risk that earnings are not smooth. This is explored further in the next research question.

B. Research Question 2. Do curative products provide market advantage? How do the markets respond to development and approval of curative products?

To assess the market response, we examined the publicly traded stocks of Gilead Sciences and comparable companies' stocks. We calculated the Sharpe ratio, which measures the risk adjusted return for a stock, between July 31, 2007 and December 31, 2016. The results show that the Gilead Sciences, which developed multiple curative products, did not have a better risk adjusted return (Sharpe ratio = 0.149) than comparable biopharmaceutical companies including Biogen (Sharepe ratio =0.162), United Therapeutics (Sharpe ratio = 0.148), Celgene (Sharpe ratio = 0.133), and Amgen (Sharpe ratio = 0.073).

Next, we examine the stock performance of Gilead Sciences during the months before and after the approval of its chronic products, Truvada in August 2004 and Atripla in July 2006 versus before and after the approval of its curative products, Solvadi in December 2013 and Harvoni in October 2014. Stock performance is measured as the stock price divided by the stock price at the starting point, which is 18 months before the approval of Truvada and the approval of Solvadi, in these two time frames, respectively. The time frame is 5 years. The results show that the stock performance exhibits the smoothly increasing profile with the chronic pharmaceuticals of Truvada and Atripla, but the undesirable peaking then dropping following the approval of curative pharmaceuticals

Solvadi and Harvoni. The results suggest that markets prefer chronic pharmaceuticals over curative pharmaceuticals.

In summary of Research Question 2, the results suggest that markets prefer a smooth revenue profile for pharmaceutical products. This presents a disincentive for developing curative products.

C. Research Question 3. Do health insurance companies prefer predictably smooth reimbursement schedules over spikes of reimbursement?

To answer this question, we again examine hepatitis C. With a hepatitis C curative pharmaceutical, from a strictly financial perspective, a health insurance payer could choose to either (1) pay a one-time cost of a curative pharmaceutic, or (2) not pay a one-time cost of a curative pharmaceutical and pay for the long-term complications as they occur years down the timeline on a probabilistic basis or each patient. Here we analyze the two choices on a per patient basis using a discounted expense analysis:

Option (1): Pay a one-time payment: the reimbursement of Harvoni is $100,000 to $120,000. Net present expense = $110,000.

Option (2): No immediate payment, but the insurance company will have to pay for long term consequences including liver failure and liver transplantation. This question was in fact studied by Bennett et al. when interferon was considered as a treatment option for Hepatitis C [8]. Bennett et al. showed that administering interferon resulted in long-term cost saving; in other words, lowering of net present expense.

Counting increased cost of liver transplant and hospitalization cost today, and the superior therapeutic effect of Harvoni to interferon, Option 1 results in lower net present expense for health insurance payers.

In summary of research question 3, paying for chronic hepatitis C patients' curative pharmaceuticals results in significant long term cost saving for health insurance payers. However, paying all chronic hepatitis C patients' curative treatments would be a "budget buster": the total cost would be more than $200 billion dollars. This is not desirable for health insurance payers.

D. Research Question (4):How can we solve the conflict: curative pharmaceutical products have better net present payoff for manufactures and payers, but their non-smooth temporal cash flow profile cause problems with market valuation of manufacturers and budgeting issues with payers.

To solve this problem, we propose the following solution: instead of making a one-time payment for each patient's usage of a curative product, the payer makes the payment in 10-year installment, to mimic the payout profile of traditional "blockbuster" drugs. The net present cash flow is the same for both the payer and manufacturer between the conventional model and the solution, but the solution is more desirable because of the smooth cash flow. For example, instead of making a one-year payment of $100,000, the payer can make a 10-year schedule of paying $10,000 per year.

CONCLUSIONS

In this paper, we investigated a factor that discourages manufacturers and health insurance payers from pursuing curative products. The results suggest that the net present value of curative products is better than chronic products for both manufacturer and payers, but markets and budgeting do not prefer curative products' non-smooth cash flows. We proposed a solution to this problem. This study was a pilot study and had limitations. The main limitation was that only a s small number of curative products are currently available; therefore, this study did not have a large sample size of curative products to study. Further study is needed to examine more curative products.

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Table 1. Statistics of Average Annual Sales of Brand Name Chronic Drugs

Average Annual Sale (million dollars)	Net present revenue (million dollars)	Percent of drugs
0 – 500	0 – 4,932	22%
500–1,000	4,932–9,863	28%
1,000–1,500	9,863–14,795	11%
1,500–2,000	14,795–19,727	22%
2,000–3,000	19,727 –9,590	17%
> 3,000	> 29,590	28%

Sample Size = 23, Mean = 2,115 (million $), Median = 1,515 (million $), Standard deviation = 2409 (millions $). For discounted present revenue of a chronic pharmaceutical with different mean annual revenue (in millions of dollars), the discount rate is assumed to be 0.05.