

UNDERSTANDING AND MANAGING PROFITABILITY IN A COMPETITIVE ENVIRONMENT: AN APPLICATION IN BIOTECHNOLOGY

by

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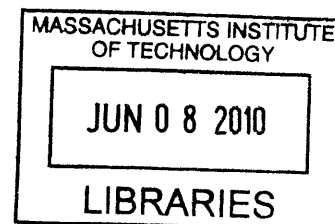
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ABSTRACT

For many biotech drugs, minimal competition has led to significant margins. Genentech's legacy product, however, faces intense competition from six other competitors. Competition necessitates contracting to ensure patient access to the product but this results in price erosion. An increase in discounting and subsequent price erosion in recent years has prompted a need to better understand account level profitability. Given a highly dynamic and complex payer and distribution network, it is difficult to determine the contribution of each vial that is sold, such that the profitability of some vials is in question. As other biotech drugs begin to face similar competitive market dynamics, an analysis of Genentech's product brings timely insight into understanding and managing profitability in a competitive environment within the biotechnology sector.

System dynamics modeling is used to analyze the key attributes of a competitive environment. It highlights two important and related observations: that increased market share does not necessarily lead to increased profitability, and that contract wins do not always result in increased sales.

A framework is introduced to determine account level profitability. By using activity-based accounting to allocate costs, the true profit of each account is determined. Results show that the degree of profitability varies widely, further reinforcing the notion that account specific profits rather than average profits are a more accurate measure of performance.

Finally, to assist decision makers in the ongoing process of promoting sound business decisions, tools are created that incorporate the insights gained in this analysis. Both an account specific marginal profit model and a dashboard will help to ensure that future decisions lead to long-term profitability.

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1 Introduction

1.1 Motivation for Thesis

For many biotech drugs, minimal competition has led to significant margins. Genentech's legacy product, however, faces a different situation. It has been commercialized for more than 25 years and faces heavy competition from six other competitors. Competition necessitates contracting to ensure patient access to the product but this results in price erosion. An increase in discounting and subsequent price erosion in recent years has prompted a need to better understand account level profitability. Given a highly dynamic and complex payer and distribution network, however, it is difficult to determine the contribution of each vial that is sold, such that the profitability of some vials is in question.

To ensure long-term, sound business decisions, it is necessary to understand account level profitability of Genentech's legacy product as well as the nature of the competitive environment in which it operates. Given current circumstances, this understanding would be beneficial not only to this product but the company and industry as well. As of last year Genentech became a member of the Roche Group and its portfolio has expanded to include other pharmaceuticals which also face a competitive environment. Within the biopharmaceutical industry, the introduction of follow-on biologics is on the horizon, which would bring lower cost drugs to market and inevitably increase competition. Therefore, an analysis of Genentech's legacy product brings to this company as well as this industry timely insights in understanding and managing profitability in a competitive environment.

1.2 Organization of Thesis

Chapter 1 describes the motivations which prompted the thesis research and the relevance of this topic to the company and biotech industry.

Chapter 2 provides an overview of the company and industry, sets the context for competition within the industry, and explains the complexity of the biopharmaceutical supply chain.

Chapter 3 uses system dynamics modeling of Genentech's legacy product to understand the dynamics of a competitive environment and explains the need to understand profits at an account level.

Chapter 4 introduces an approach and framework to calculate account profitability, and then analyzes the resulting profits.

Chapter 5 draws upon insights from Chapters 3 and 4 to present tools that assist in effective decision making in the context of managing for profitability

Chapter 6 summarizes recommendations and key findings

2 Background

2.1 Genentech, Inc.

Genentech has been a leader in the biopharmaceutical industry for more than 30 years. Since its founding in 1976, Genentech has been using genetic information to discover, develop, manufacture and commercialize medicines to treat patients with serious or life-threatening medical conditions. Today Genentech is among the world's leading biotech companies, with multiple products on the market and more than 100 projects in the pipeline¹.

Genentech's goal is to deliver innovative medicines. The company's research organization has historically focused its drug discovery efforts on therapies that would fill unmet medical needs². As a natural consequence of this vision, many of its products were launched into markets without considerable competition. In March 2009, Genentech became a wholly owned member of the Roche Group. As part of their merger agreement, Roche and Genentech combined their pharmaceutical operations in the United States. Accordingly Genentech's product portfolio now includes products which were previously marketed as Roche products – some of which serve more competitive therapeutic areas.

Genentech employs more than 11,000 personnel and in 2008 posted product sales of \$10.5 billion, with \$2.8 billion invested to research and development³. Genentech is headquartered in South San Francisco, CA which also serves as the headquarters for Roche pharmaceutical operations in the United States.

2.2 Biotechnology Industry and Specialty Products

2.2.1 Overview

From the discovery of recombinant DNA technology in 1973, the biotechnology industry was born. Biotech drugs or biopharmaceuticals are pharmaceuticals or vaccines that have been produced in living organisms and manufactured by recombinant DNA technology⁴. Unlike traditional drugs which are generally produced through chemical synthesis and taken orally, drugs produced through

¹ (About Us, 2009)

² (Medicine, 2010)

³ (Genentech, Inc., 2008)

⁴ (IMS, 2008)

biotechnology have a significantly larger and more complex molecular structure and are typically injected.

As a result, biotech drugs typically fall into the category of specialty products, a category that has come to define pharmaceutical products used to treat specific chronic, genetic, complex health conditions, such as cancer, rheumatoid arthritis and multiple sclerosis. Specialty products are high cost, high touch products. Costs range from \$6,000 to \$250,000 per patient per year⁵. The products require special handling procedures such as cold chain distribution, and necessitate close patient monitoring and education.

The specialty products market is a rapidly growing market, with sales totaling \$71 billion in 2008, making up 25% of overall pharmaceutical sales⁶. In 2007-2008, the FDA approved 23 specialty medications across multiple diseases, and with more than 600 specialty medications in various stages of development, the specialty market is expected to top \$87 billion by 2011⁷.

2.2.2 Competition

Continued growth in the specialty market is projected, though its future will be predicated upon several key market dynamics, including growing competition among biotech products as well as emerging competition from follow-on biologics⁸.

Competition is greatest among biotech products in areas where the products are viewed as therapeutically equivalent. This is already the case for several therapeutic areas such as hGH deficiency, hepatitis, and chronic immunological disorders (psoriasis, multiple sclerosis, rheumatoid arthritis, and Crohn's disease)⁹.

Economic pressures for lower cost specialty medicines continue to increase and follow-on biologics are expected to impact the market within the upcoming years. Follow-on biologics, or generic biologics, face stronger barriers to entry than chemical drugs due to significantly more complex and extensive manufacturing processes, higher cost of materials, and a need for more clinical trials to

⁵ (Health Strategies Group, Spring 2009)

⁶ (Health Strategies Group, Spring 2009)

⁷ (Health Strategies Group, Spring 2009)

⁸ (IMS, 2008)

⁹ (Health Strategies Group, Winter 2008)

meet safety concerns¹⁰. Yet their introduction will inevitably result in price pressures and increased competition following the loss of exclusivity of original products.

2.3 Biopharmaceutical Supply Chain

The biopharmaceutical supply chain is a complex and evolving network of multiple stakeholders, including drug manufacturers, distributors, third-party payers, pharmacy benefit managers (PBMs), physicians and patients. A simplified drug distribution model with product, payment and discount flows is shown in Figure 1.

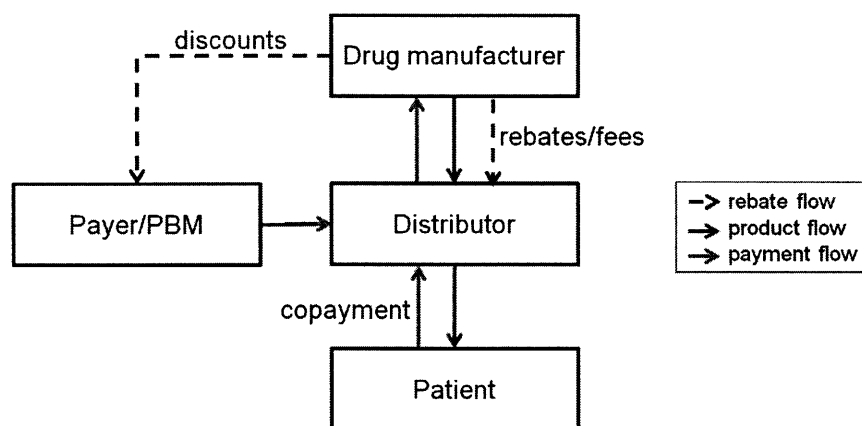


Figure 1: Flow of products and financial transactions in the biopharmaceutical supply chain

2.3.1 Flow of Products

The drug originates at the manufacturer and is then shipped through a variety of distributors. Distributors include drug wholesalers, specialty pharmacies, mail-order pharmacies, retail pharmacies, hospital chains and physician’s offices. Rarely are drugs distributed directly to the patient. The product may travel through one or more of the above entities before reaching the end user.

The distribution network continues to undergo significant change and consolidation. Between 1975 and 2000, wholesalers in the U.S. have consolidated from approximately 200 to fewer than 50 firms¹¹, and are now dominated by three companies. Since 2004, the list of top specialty pharmacies

¹⁰ (Health Strategies Group, Fall 2008)

¹¹ (Goldman Sachs, 2003)

has changed by more than 50% due to mergers and acquisitions¹², with eleven independent¹³ and five Managed Care Organization (MCO)-owned specialty pharmacies¹⁴ now leading the industry. This continuously changing landscape poses a challenge for manufacturers when trying to understand the channels the product utilizes in order to reach the patient.

2.3.2 Flow of Financial Transactions

The flow of financial transactions is more complex than the physical distribution of products. As one leading journal states, “prescription pharmaceuticals are unlike any other segment of the health care marketplace in the complexity and variation of how the finished goods are priced to intermediate and final purchasers in the channels of distribution and ultimately how much is paid when the product is dispensed or administered to the patient.”¹⁵

The entity not included in the physical distribution of the product but which is instrumental in financial transactions is the payer/PBM. Third-party payers are private insurers, self-funded employers and public health programs¹⁶. PBMs provide various services to payers, ranging from claims adjudication to managing drug utilization. The drug manufacturer directly interacts with both payers and PBMs.

When the drug manufacturer sells the product to the distributor, a financial transaction takes place as the distributor pays a negotiated amount to the manufacturer. Pharmacies will in turn receive a payment from the payer or PBM when the drug is dispensed to its plan member. Patients with health insurance coverage will pay a cost-sharing amount for the drug, such as a flat copayment, to the pharmacy or at the point of sale.

The drug manufacturer may negotiate contracts with both distributors and payers/PBMs for a myriad of services at a wide range of discounts, rebates and fees. These financial transactions take place over different time periods, either instantaneously as a discount off of invoice price, disbursed retroactively after several quarters, or paid as a flat fee upon service completion. Examples include:

¹² (Health Strategies Group, Spring 2009)

¹³ (Health Strategies Group, Spring 2009)

¹⁴ (Health Strategies Group, Spring 2009)

¹⁵ (AMCP Task Force on Drug Payment Methodologies, 2009)

¹⁶ (The Health Strategies Consultancy LLC, 2005)

- **Market share rebates:** paid to the distributor or payer based on its ability to manage product utilization
- **Volume discounts:** paid to the distributor or payer when predetermined sales volumes are met
- **Prompt pay discounts:** paid to distributors when payments are received on time
- **Service/administrative fees:** paid to distributors for services, e.g. nursing services, product sales data, compliance/persistency programs

Depending on the drug being distributed, the manufacturer may or may not use any of the above contracts. For example, a manufacturer would not contract with a payer/PBM to direct drug utilization if the drug under consideration is not in a competitive therapeutic area. Also the relationship and level of discounts for commercial payers and governmental institutions would also vary.

Important to note in Figure 1 is that there are two cost transactions originating from the manufacturer – one to the payer/PBM, and the other to the distributor. Since these price concessions are a result of a variety of negotiated contracts and vary in magnitude, each vial that travels through this supply chain may see a substantial variation in price.

2.3 Chapter Summary

The biopharmaceutical industry has grown tremendously since its inception and foresees increasing competition due to therapeutic areas becoming more crowded, as well as the introduction of follow-on biologics on the horizon. The distribution system is a complex network with varying discounts and constantly evolving players. It is difficult to track each vial as it flows through the channel and even more difficult to determine the end price charged to each vial. As discounts increase due to competition, the question exists as to whether some vials might be sold at a loss.

Genentech is a leading biotech company with a legacy product that is one of the oldest biopharmaceuticals on the market and faces competition in a therapeutically equivalent area. In this context an analysis using this product can provide valuable insights into understanding and managing profitability in a competitive environment.

3 Understanding Competitive Dynamics through System Dynamics Modeling

The purpose of this chapter is to understand competitive dynamics by analyzing the historical events of Genentech's legacy product through system dynamics modeling.

3.1 Background of Events

Genentech's legacy product is the company's oldest marketed product and has been commercialized for 25 years. It was the first in its therapeutic class and has been the market leader ever since.

Throughout the years other manufacturers have entered the market, with now seven competitors in total, but the largest shift in market dynamics occurred during the middle part of the last decade. A combination of events transpired resulting in increased competition and price erosion.

The first event was the arrival of a new entrant into the market, a low-cost competitor who offered payers discounts at double-digits below what other manufacturers were offering. Payers began to request that incumbents match the prices or risk being removed from their formularies. A second cause of disruption was the change in behavior of a current competitor, who started to approach payers and distributors with deep discounts in exchange for exclusive formulary status. While it was common for payers to have several products on its formulary, this competitor was offering payers large discounts in order to be the only product on their formulary. In doing so it would guarantee usage by the patients covered under that payer. Lastly, whether it was a result of manufacturers' actions or a reflection of changing industry conditions, payers began to manage the therapeutic class more closely and specialty pharmacies also began to offer the ability to drive market share. All of these changes resulted in intense price competition and a drastic erosion of overall manufacturers' profits.

As Genentech has recently acquired more competitive products after joining the Roche Group, and the biopharmaceutical industry anticipates increased competition upon the introduction of follow-on biologics, it is beneficial to learn from the competitive events surrounding Genentech's legacy product in order to assist future business decisions taking place in a competitive environment.

3.2 Overview of System Dynamics Model

System dynamics modeling is used to assist in this analysis. System dynamics is an approach to understanding complex systems and enhances learning by integrating information in such a way as

to highlight causal relationships and feedback loops, and to reveal our mental models and the unintended effects of our decisions¹⁷.

When constructing the model, Genentech's legacy product was used as a basis to determine which variables to incorporate into the model, as well as the characteristics of those variables. By inserting the product's unique parameters, the model is representative of a commercial payer account and designed to be applicable for any specialty product. A simplified version of the model is shown in Figure 2 for discussion purposes, while the full model with equations is included in the Appendix.

Conceptually, the model is divided into four parts. Starting from the bottom of the figure and moving counterclockwise it illustrates the interactions between the arrival and departure of patients on therapy, performance indicators observed by the organization, key decision variables, and product adoption drivers, which are briefly discussed below.

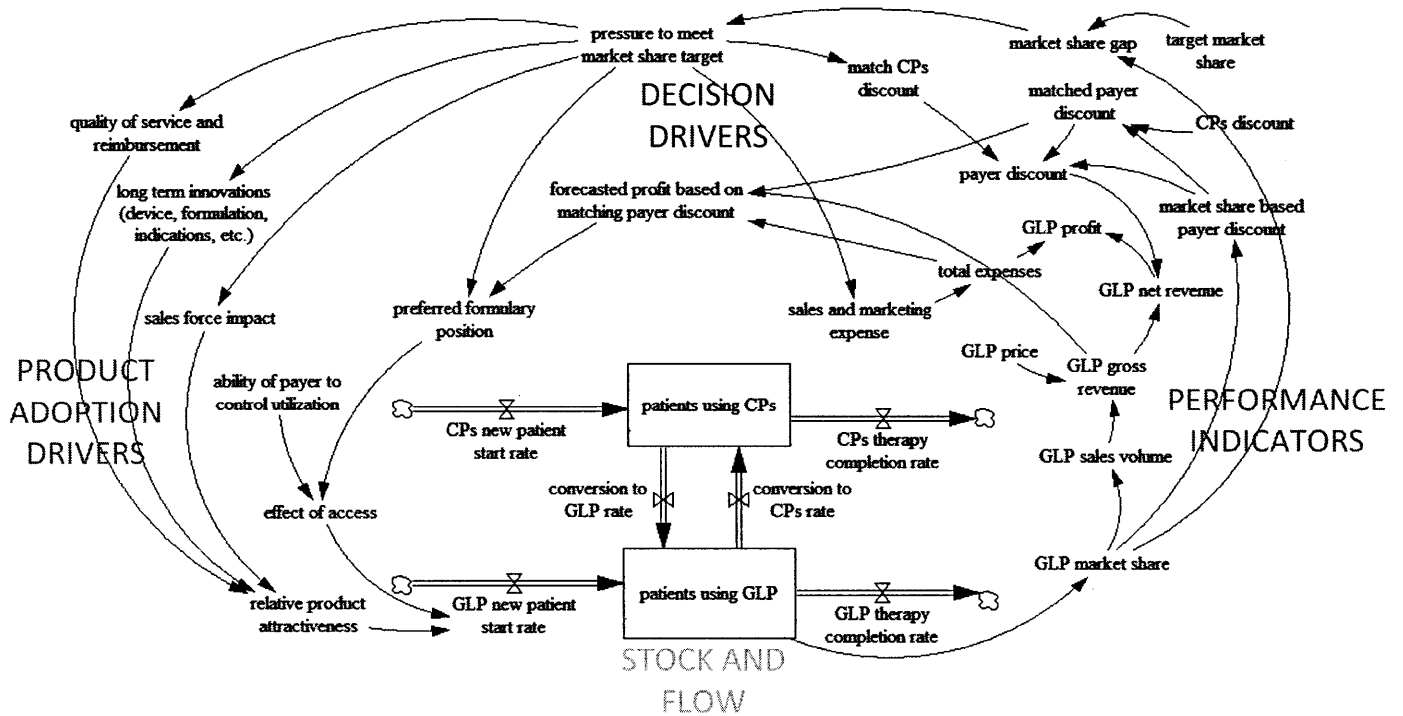


Figure 2: Simplified version of system dynamics model

¹⁷ (Sterman, 2000)

Stock and Flow

The stock and flow is the process in which new patients begin using the product and then finish using the product once therapy is completed. New patients are continuously diagnosed for a variety of diseases. The rate at which a new patient is diagnosed for a particular therapeutic area is dependent on the size of the payer account and the rate of diagnosis. The rate of diagnosis depends on the prevalence of that particular disease, the fraction of the population affected. The more covered lives there are under that payer account, the greater number of people that would be diagnosed in a given time period. As the model shows, once a patient is diagnosed, the patient is either initiated on Genentech's legacy product (GLP) or a competitor's product (CP). From there it is likely that the patient will continue on that product for the duration of the therapy. This differs from oral medications where conversion programs are much more common. As biotech products and the diseases in which they treat are more complex, there can be serious complications if the conversion is not managed appropriately. Biotech products are also more complicated to administer. Patients and primary care physicians who have developed familiarity with the product and injection device may be reluctant to switch to another product. As a result, patients are more likely to use the same product for the duration of the therapy, and even if their payer switches preferred products on their formulary, the patient is typically "grandfathered" so that the same product can be used until therapy completion.

Performance Indicators and Decision Drivers

As patients start or complete therapy, the drug manufacturer receives indications of product utilization, as it affects market share, gross revenue, net revenue, and profit. Gross revenue is a function of volume and price, and therefore will increase as more patients use the product or due to price increases. Net revenue is a function of gross revenue and discounts. The discounts modeled are tiered based on achieved market share so that as the product's market share increases for that payer, the level of discount also increases. Profit is net revenue less total expenses. Throughout this process there is an information delay due to the time required to receive, process, and disseminate information. As a result, perceived performance will lag actual performance. When evaluating product performance, the perceived performance is compared to the company's desired target performance. A difference between the two results in a gap, and the larger the gap the more pressure there is to close the gap and meet performance metrics. Depending on what the company uses as its performance metric, different actions are taken.

Product Adoption Drivers

There are two variables which impact whether a new patient adopts the product – access and attractiveness. Access is based on inclusion in the payer’s formulary and how effective the payer is in managing utilization. Payers and PBMs use formularies to control product use. A formulary is a list of drugs which the payer or PBM considers as preferred for use in treating patients served under their plan. For non-preferred drugs, patients bear a higher financial burden. Therefore, payers can steer product utilization via inclusion or exclusion on the formulary. Payers currently evaluate the inclusion of drugs by comparing them on safety, efficacy and cost. For products in therapeutically equivalent areas, however, where safety and efficacy are comparable, decisions often reflect lowest unit cost. Payers negotiate with drug manufacturers for rebates to lower drug costs in exchange for inclusion in the formulary. Among specialty pharmacy products there are typically fewer drugs in each therapeutic class making it more difficult for payers to leverage products against each other as with traditional drugs, but as therapeutic areas become more crowded, as in the case of Genentech’s legacy product, the increased competition gives payers more options and enables them to negotiate with manufacturers for higher discounts.

Inclusion on the formulary provides drug access to plan members, but as there are typically several preferred products for the same therapeutic area, product attractiveness then becomes an important driver for adoption. Product attractiveness is a function of many different variables, such as the quality of service and reimbursement, the attributes of the product itself, and the sales and marketing efforts which make people aware of those characteristics. Some of these qualities can be improved in a short time frame based on the gap between perceived and expected targets, while some innovations will not see results for several years. In this model the product becomes more attractive as the quality of service and reimbursement increases. The level of educational and clinical support eases the process as new patients begin therapy and continue therapy, and an effective reimbursement program streamlines the process for all parties. The improvement in this area can be accomplished in the short term, from several months to train new personnel to years to install new information technology systems. Improvement of other variables, however, involves more research and development, and results are not seen for several years. These features include innovations for a new drug formulation, conducting clinical trials to approve the drug for a new indication, and designing a new injection device. These features are important for the long-term sustainability of the product, but are unlikely to affect performance metrics in the short run. Aside from product

attributes, promotional activities and the sales force also play an important role in bringing awareness of product features to the physicians, nurses and patients. All of these features combined impact the rate of new patient adoption.

3.3 Using the Model to Understand Competitive Dynamics

During the course of increased competition for Genentech’s legacy product, two observations were made regarding contract wins and competition for market share. This section uses the model to understand those observations.

3.3.1 Contract Wins and Sales

With many clinically equivalent drugs in a therapeutic area, payers are able to leverage products to obtain higher rebates in return for preferred formulary status. Drug manufacturers negotiate contract terms with payers in order to win bids because as a preferred product, it would have a greater likelihood of usage by the payer’s patients. For example, for a formulary with three preferred drugs, each of those drugs is competing essentially with only two other products instead of all six competitors. Our mental model tells us that if we win the contract, the drug will become a preferred product, the patient will have access to a limited number of preferred products, of which one is ours, and sales will increase (Figure 3).

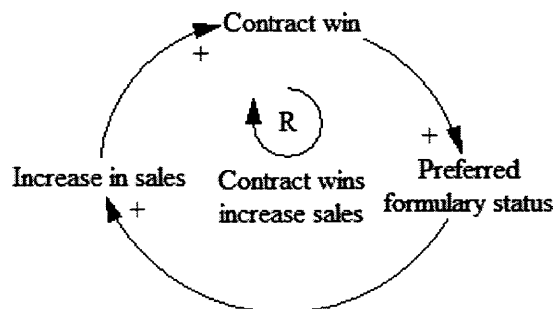


Figure 3: Mental model of contract win-sales relationship

A review of current contracts, however, reveals that sales do not always improve with preferred access, with the converse also true. There may be several reasons. First is the factor of how effectively the payer is able to control product utilization. Payers use different methods to direct utilization, such as higher copayments or coinsurance for products not on the formulary, using prior authorizations, step edits, or actively converting patients to drugs on the formulary. The degree to which a payer actively manages drug utilization impacts product adoption for drugs that are

preferred or non-preferred. Figure 4 shows the impact of payer control on sales volume for a product on the formulary. As payer management intensity increases, there is a greater impact on sales for products that are on the formulary.

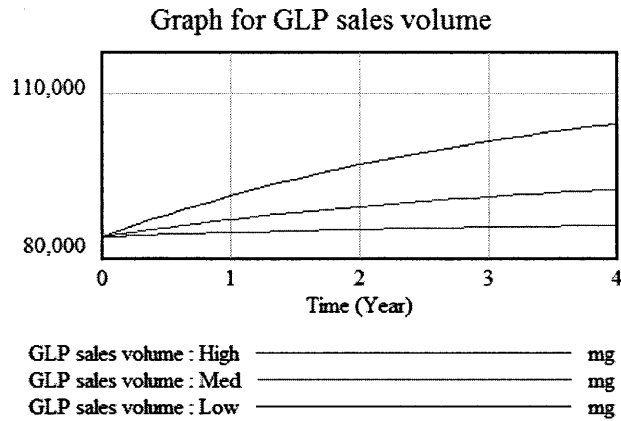


Figure 4: Impact payer product utilization control on sales volume

As one leading report stated, “MCOs offer to drive up market share for contracted products in return for rebates and discounts... manufacturers must determine MCO’s ability to steer product usage before offering price concessions.”¹⁸ It is most advantageous to be a preferred product on a formulary where the payer employs methods to actively direct product usage. For products not on those formularies, access will be very limited. Alternatively, if a payer does not actively manage utilization, being a preferred product may not have much impact.

A second factor that plays a role in translating contract wins to increasing sales volume is product attractiveness. As seen in the model, both access and product attractiveness are inputs into new patient adoption. The contract win affects access, but as there are likely other preferred products on the formulary, the characteristics which differentiate the drug from competitors’ products will influence product adoption. Even if a product does have more favorable attributes, however, those attributes need to be known in order for it to influence product use. Therefore, the sales force plays a role in bringing awareness of the product and in highlighting its key characteristics. Understanding the various factors influencing product adoption explains why contract wins do not naturally translate to increased sales. The payer’s ability to manage utilization in conjunction with awareness

¹⁸ (Health Strategies Group, Winter 2008)

and product attractiveness will influence the relationship between contract wins and increases in sales volume.

3.3.2 Market Share and Profitability

In analyzing the outcomes of past events, another observation involves the relationship between market share and profitability. Contrary to common reasoning, an increase in market share does not necessarily lead to an increase in profits. Focusing too much on market share can actually have a negative impact on profits. There is a conventional approach which says, “Gain market share and profitability will follow”¹⁹, but as one researcher concluded, “It appears that the hypothesis which maintains that there is a positive correlation between market share and profitability...resulting from a causal relationship between the two variables, is an oversimplification which contains a number of dangers.”²⁰

One of these dangers is when a company focuses on maximizing market share with intent on maximizing profits. For a product such as Genentech’s legacy product which operates in a mature market, if the company intends to increase profits it may be a mistake to use market share as a profit indicator. Our mental model of the causal relationship between the two variables is depicted in Figure 5.

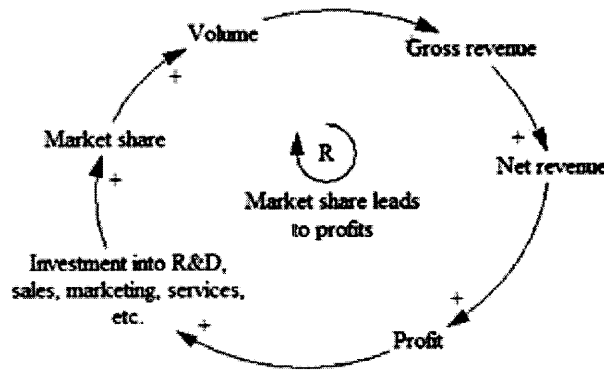


Figure 5: Mental model of market share-profit relationship

The thought is that if we increase market share, our product volume will increase, leading to higher gross revenues and net revenues which will ultimately lead to greater profits. As profits increase, we

¹⁹ (Slywotsky & Morrison, 1997)

²⁰ (Bourantas & Mandes, 1987)

are able to make more investments into the business which would help to gain market share once again and then continues the virtuous cycle. In many cases this is true, especially for many biotech drugs which experience small discounts and high margins; as market share increases, so do profits. As discounts grow, however, the product may reach a point where net revenue does not directly follow gross revenue. As shown in Figure 2 one important variable not included in our mental model is discounts. The company may increase discounts while chasing after market share in order to win contracts, but at some point the level of discounting may outpace the growth in volume, and at this point trends in gross revenue and net revenue will diverge. In this situation an increase in market share does not lead to an increase in profits and market share no longer becomes a viable indicator of profitability. This scenario is shown in Figure 6, which models a company chasing after market share and matching competitors' increasing discounts.

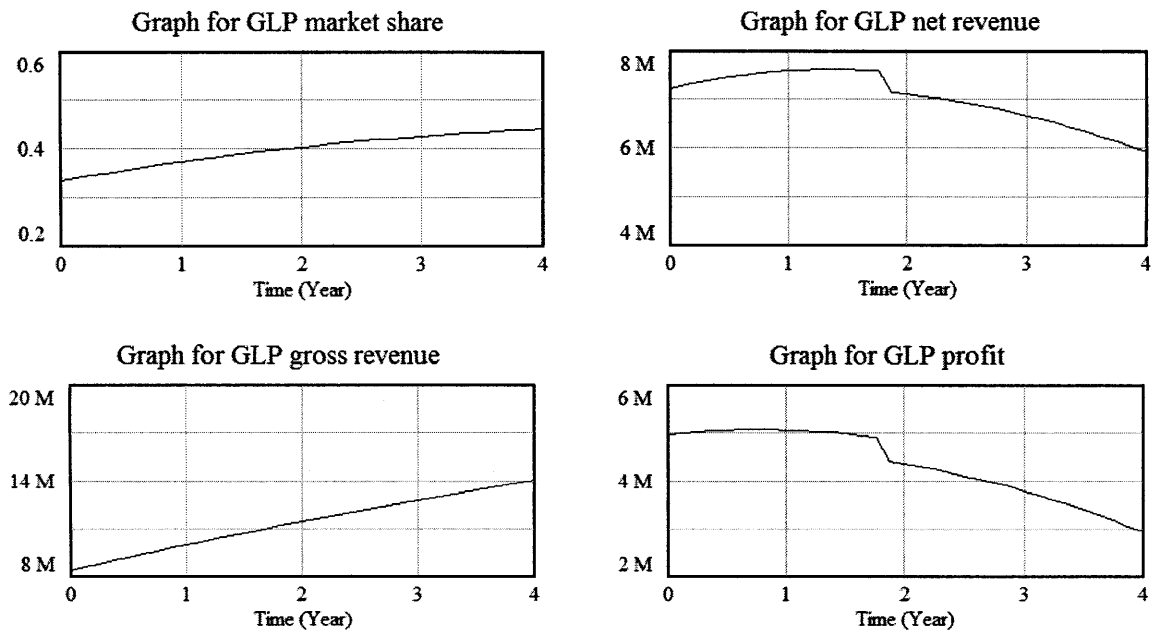


Figure 6: Disparity in gross and net revenue arises as discounts exceed volume growth

As seen in the figure, market share and gross revenue continue to grow, but net revenue and profit exhibit a concave profile. Profit follows market share until around year one, at which point discounting outpaces volume growth. At that point, profit begins to decline while market share continues to increase. The graphs also show a characteristic inherent to tiered rebate terms with the discontinuity in the net revenue and profit graphs. Rather than a flat discount percentage, the contract between the drug manufacturer and payer may specify increasing discounts based on

achieving higher market share tiers. In this scenario, the discount increases incrementally when reaching a predetermined market share, accounting for the sharp decrease in net revenue and profits. As shown in this example, if the company focuses on market share as the profit indicator, the decrease in profits may initially go unrealized.

Many examples abound of companies in various industries which have faced this disparity between market share and profits. In 2005, one analyst commented that the Ford Motor Company needed to watch profit as well as share. Ford was replacing a lot of its midsize and large SUVs and trucks with less profitable cars. The result was that “they could stabilize or even increase market share and still see profit continue to drop.”²¹ In 2007, the LCD market was suffering from profit erosion despite increasing gross revenues, consistent with the graph above. Jun Souk, the Executive Vice President of Samsung Electronics LCD business unit explained that prices continued to be cut and the increase in sales volume could not compensate, causing profits to decline further²². This was the same scenario as above where the rate of discounting was greater than the rate of change in volume.

Aside from market share not being an accurate indicator of profits, a second danger of focusing too much on market share is that it can actually harm profits as business decisions are made based on out-performing the competition rather than on long-term profitability, which as seen above is not always aligned. Competitor-oriented activities such as competing for market share often result in short-term solutions such as price competition, which tends to erode the entire market. In the LCD example above that was exactly the case. The reason LCD prices were cut and profits declined was because the five major LCD manufacturers were competing to increase market share²³.

Competitor-oriented objectives can negatively impact profits as the company strives to out-perform the competition. With pharmaceutical drugs, competing for market share in the commercial sector based on increasing discounts can inadvertently also lower profits in the government sector as they impact Medicaid rebate requirements. Numerous lab and field studies have been conducted showing that when people try to do better than their competitors rather than simply focusing on doing the best they can, they make decisions which are counterproductive, in turn decreasing their

²¹ (Koenig & Ohnsman, 2005)

²² (Morgenthal, 2007)

²³ (Morgenthal, 2007)

own profits²⁴. Around the same time that Genentech's legacy product was experiencing price pressures General Motors was subjecting itself to one of the largest discount battles in history. Its actions forced its competitors Ford and Chrysler into a price war that had little effect other than destroying profits. In the end not only did the minimum target remain unfulfilled, but GM's market shares sunk even further²⁵.

Competitor-oriented activities pursue short-term results and companies have acknowledged the danger of competing in them. Ergo, the second largest insurance group in Germany, had announced in a press conference that it would stay out of a price war and also accept some loss of market share²⁶. GM, several years after the price war, concluded that "within reason it would be better to sell slightly fewer [vehicles] at higher margins. We've tried to sell more at lower margins and it's what got General Motors into trouble."²⁷

The conclusion is that market share does not always lead to profits and that long-term profitability is a result of customer and profit oriented management rather than market share oriented management. As shown in Figure 2, many innovations which improve product attributes take several years to have market impact. However, if the company is customer-oriented it will focus on creating value for the industry rather than merely trying to capture value, and market share should follow. Toyota is one company which has adopted this mind set. As Kazuo Okamoto, executive vice president at Toyota explained, "We aren't that concerned about vehicle numbers, but we are determined to go at it to develop cars that make a lot of people happy."²⁸

3.4 Challenges and Motivations in Understanding Account Profitability

The result of this analysis is that the company needs to base decisions on profitability. However, when making decisions about a particular payer account, the question then arises as to how to determine actual account profitability. On average the product is profitable, but with increasing discounts at varying levels and a complex and dynamic payer and distribution network, it is difficult to determine the actual profit of each vial that is sold, to the extent that it is uncertain whether some vials are actually being sold at a loss.

²⁴ (Armstrong & Green, 2007)

²⁵ (Bilstein & Simon, 2007)

²⁶ (Bilstein & Simon, 2007)

²⁷ (Bilstein & Simon, 2007)

²⁸ (Knowledge@Wharton, 2007)

To understand how this may be possible, consider a simple illustration for a product with only two payer accounts and two distributors, with equal volumes and the following discounts:

Specialty Pharmacy A: 5%	Payer X: 20%
Specialty Pharmacy B: 15%	Payer Y: 60%

In this scenario, the average distributor discount would be 10%, and the average payer discount would be 40%. If unit costs are 30% of list price, the company would make an average profit of 20% on each vial²⁹. As in this scenario, however, there is a wide range of discounts and it is difficult to determine the relationships between payers and specialty pharmacies and the actual costs attributed to each vial. For example, the patient may be covered under Payer X which happens to use Specialty Pharmacy A, or any such combination. In this illustration, suppose Payer X only uses Specialty Pharmacy A and Payer Y uses Specialty Pharmacy B. Then a vial dispensed to a patient covered under Payer X would have a marginal profit of 45%, while a vial dispensed to a patient covered under Payer Y is actually sold at a 5% loss³⁰, results which are drastically different from the 20% average profit.

This illustration alludes to the challenges in determining account profitability and highlights the need to understand not just average profits, but account level profits. These challenges and motivations are described in more detail below.

3.4.1 Challenges

There are two main challenges in determining account level profitability – determining the effective discount given to each payer and distributor and then being able to link the two together.

The variety of discounts, rebates and fees

In the illustration above, the discount for each account was given, but in actuality there are numerous types of price concessions and it is a challenge to determine the total effective discount offered to each account. Price concessions come in different forms, in a range of values, and over different time periods. Whereas a prompt pay discount is a deduction off of invoice price, a market share rebate is paid to an account several quarters later and varies in percentage quarter to quarter

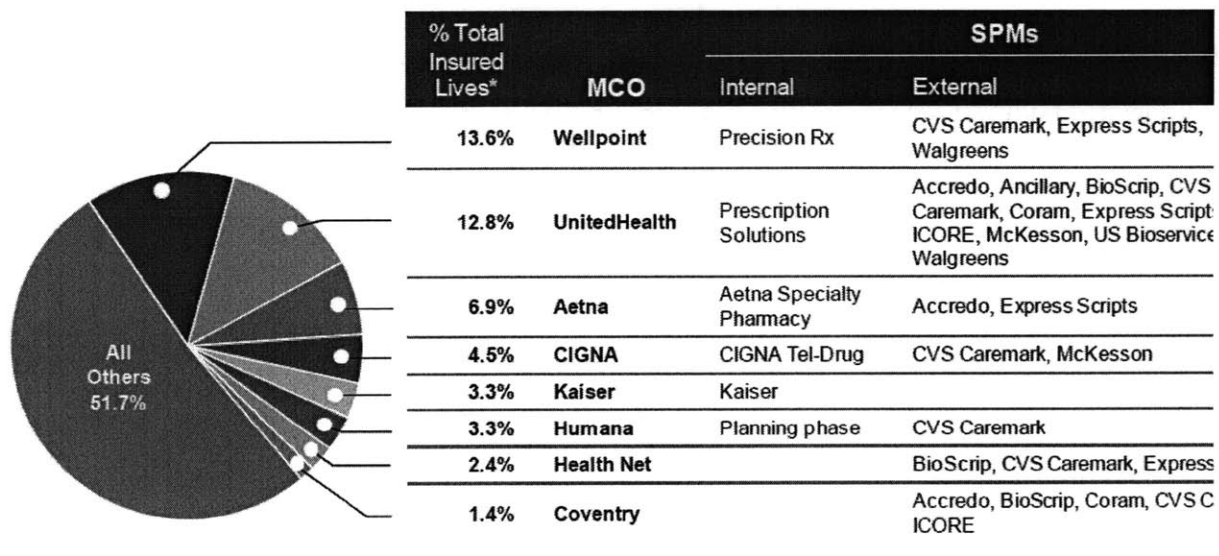
²⁹ Average distributor discount = $(5+15)/2 = 10\%$, Average payer discount = $(20+60)/2 = 40\%$, Average cost = $10+40+30 = 80\%$, Average profit = $100-80 = 20\%$

³⁰ Profit of vial covered by Payer X = $100-20-5-30 = 45\%$, Profit of vial covered by Payer Y = $100-60-15-30 = -5\%$

depending on account performance. Contracts are also periodically renegotiated, which can alter the discount terms at various points in time. These factors pose a challenge to understanding the total effective discount given to any one entity in any one period. Furthermore since there is a large range of discounting among accounts, as in the illustration, it is inadequate to simply estimate an average discount for determining account level profits.

The difficulty of linking distributors and payers

The second challenge in determining account profitability as seen in the previous illustration is being able to link distributors to payers. In a network of only two payers and two distributors there are only two possible combinations if each payer uses a sole distributor. But if each payer uses a mix of distributors and the network is expanded to include several hundred payer and distribution accounts, the complexity and possibilities are magnified. Figure 7 shows that the five largest managed care organizations (MCO), or payers, own an internal pharmacy. That is their primary pharmacy and preferred distributor. The figure also shows, however, that even when payers have an internal pharmacy, each also utilizes a diverse network of external specialty pharmacies as well.



*Total insured lives in 2008 = 257,340,000
Source: Company reports.

Figure 7: Leading MCO and specialty pharmacy networks (Health Strategies Group, Spring 2009)

As a result, it is difficult to determine exactly which distributors are used by each payer and to what extent. Furthermore, the biopharmaceutical supply chain continues to evolve as new distributors emerge and existing ones consolidate through merger and acquisitions. Relationships between

payers and distributors continue to change as well. Therefore, even if the first challenge of determining distributor and payer discounts is overcome, linking the two together presents another challenge.

3.4.2 Motivations

With the potential for large disproportionality in profits across accounts, understanding profits at the account level ensures that vials are not sold at a loss and informs which accounts are contributing the most to the business.

Ensure that vials are not sold at a loss

In order to maintain long-term profitability so that the company can continue its purpose in serving patients, it is necessary to ensure that vials are not being inadvertently sold at a loss as in the case of Payer Y in the illustration. With most biotech drugs, high margins curtail this as even being a possibility, but with increased competition and subsequent discounts, it becomes more of a concern. At the border between a marginal profit and marginal loss, a very small pricing difference could result in a considerable change in total profits; as long as each vial generates a small profit, each subsequent sale will increase profits incrementally. On the contrary, if that vial is sold at a small loss, each subsequent sale will cause a downward spiral in profits. Since each contract is negotiated between the drug manufacturer and the payer to determine discount terms, it is necessary to know one's reservation value to ensure that contract terms are profitable. Without knowing the profitability of the account, the drug manufacturer could potentially offer a discount beyond the reservation value in an effort to match competitors' discounts and win the bid, but as a result sell the product at a negative marginal profit. Therefore, understanding account level profit is necessary to ensure that vials are not being sold at a loss and that contract wins are profitable.

Determine the contribution of each account

The illustration with Payer X and Payer Y also shows that there can be a large disparity in the profits realized by each account. In determining which accounts contribute the most to a business, an empirical study conducted by Wengler et al. examined the criteria used by different companies. Results show that 80% of companies select their key accounts based on sales volume, 40% use the customer's market share, and only 30% also take into consideration the customer's contribution

margin (CCM), a basic tool for assessing profitability³¹ (Figure 8). As was determined in the illustration with Payer X and Payer Y, profitability should be the criterion in determining key accounts. Volume is not an accurate criterion since all vials are not equally profitable. If volume were used in the last illustration, both payers would appear equally profitable since they had the same volume, but as the illustration showed, they were not and in fact Payer Y actually had a negative contribution to the business.

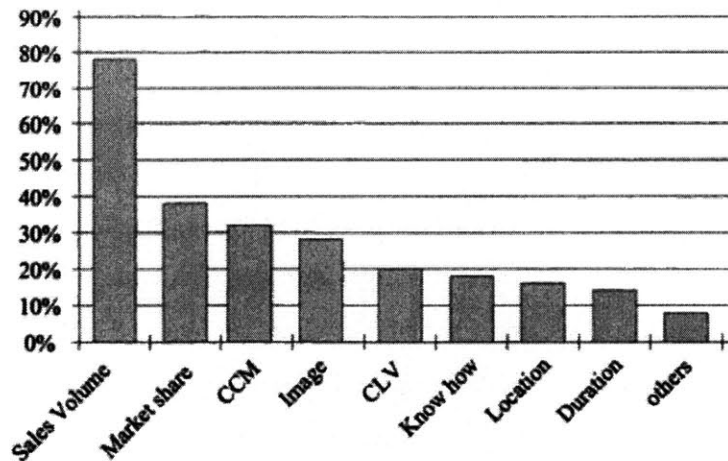


Figure 8: The use of criteria for the selection of key accounts (Wengler, 2006)

Using improper criteria and not understanding account profitability results in companies misinterpreting account contribution and keeping unprofitable accounts such as Payer Y. Research conducted by Cooper and Kaplan found that in some companies up to 225% of the profits are generated by just 20% of customers, a large number of customers are breakeven, and the least profitable 20% of customers lose 125% of the profits actually earned by the company³². Another study conducted for a hotel indicated that 46.5% of the revenue base was generating a 269% of total profits, with 53.5% of the revenue base generating a negative contribution equivalent to 169% of total profits; management at the site was unaware of the scale of the profits and losses generated by the customer groups³³. In these cases, as in the illustration, the profitable accounts are actually subsidizing the loss of unprofitable accounts. In an effort to drive volume, increase market share, or win competitive bids, companies may be inadvertently selling at a loss.

³¹ (Wengler, 2006)

³² (Cooper & Kaplan, 1991)

³³ (Krakhmal, 2006)

To prevent the above scenarios from occurring, it is necessary to understand profitability at the account level and not just the total average profit of the product. This ensures that all accounts have a positive contribution. It also informs which accounts are contributing the most to the business so that the company can evaluate tradeoffs and decide where best to allocate resources.

4 Calculating and Analyzing Account Profitability

As the previous chapter described, there are compelling reasons to understand account profitability. This section describes an approach to calculate and analyze account level profits by using Genentech's legacy product as an example.

4.1 Determining Types of Costs

The first step in calculating account profitability is to determine applicable costs. Costs are usually divided into two categories: *fixed* and *variable*, which describe the behavior of the cost. Fixed costs are constant and do not vary with the volume of product produced or sold, such as office space and leased equipment. Variable costs are incurred at the production of each incremental vial, for example the raw material of the drug and the vial which holds the drug. Other costs which are not used in this analysis are step-variable costs and mixed costs. Step-variable costs are expenditures which are fixed over a certain range of output levels. An example is purchasing a new machine to increase output. A machine may have a rated output but once its capacity is met an additional machine would need to be purchased. Mixed costs are costs which are not easily categorized as fixed or variable, such as electricity for a highly automated firm where a base amount is utilized but increases substantially depending on product output. When allocating these costs, the costs are considered *direct* or *indirect*. Direct costs are traceable whereas indirect costs cannot be assigned to the applicable object. Indirect costs are costs for shared services and are more commonly termed overhead. Direct and indirect costs can be either fixed or variable.

In order to determine whether a cost is fixed or variable, direct or indirect, it is necessary to define the *cost object*. The behavior and nature of the cost are all relative to the cost object, which is the product, process or program that one wishes to cost. In this analysis, the cost object is the payer account. On a more macro level, one could choose Genentech's legacy product to be the cost object, or on a more micro level it could be the cost of each vial. These cost objects, however, would not provide the relevant information one needs to make decisions on profitability. It is already known that Genentech's legacy product is profitable overall, but due to discount variability it is unknown whether it is profitable across all accounts. Likewise, a payer account may use various distributors that receive varying level of discounts so if the cost object is each individual vial, the profits would vary across vials for each payer account depending on the distributor used. Determining profitability to this level of detail, however, is not beneficial since the drug

manufacturer has little control over the distributor that the payer uses and thus cannot change those individual costs even if they were known. Therefore, the chosen cost object for this analysis is the payer account because it can influence decision making and control.

Knowing the cost object allows one to categorize costs in the following manner:

Direct variable costs: Costs which are incurred at the production and sale of each incremental vial and can be directly traced to a payer account.

1. Contracted payer discount: This is a percentage discount off the list price of each vial, usually given to a payer based on achieved market share with the purpose of managing product utilization.
2. Production: These costs are incurred at the production of each individual vial, such as the cost of the drug, vial glass and labels.
3. Marketing and sales: Costs tied to product volume, such as sales commission.

Indirect variable cost: Costs incurred at the production and sale of each incremental vial but cannot be easily traced to a payer account.

1. Average distribution discount: These discounts are paid to the distributors used by that particular payer. Examples include volume discounts, prompt pay, flat rebates, and are also a percent discount off the list price of each vial.

Indirect fixed costs: Costs shared among all accounts and cannot be easily linked to a specific payer account.

1. Distributor FTE: The allocated full-time equivalent (FTE) cost of personnel managing the distributor account to which the payer is linked.
2. Distributor service fees: The allocated fees of the distributor account to which the payer is linked. Includes fees such as administrative fees and nursing service fees.
3. Payer account FTE: The allocated full-time equivalent (FTE) cost of personnel managing the payer account.
4. Other overhead (Marketing and Sales, Production, R&D): All other overhead costs allocated to Genentech's legacy product

As seen when categorizing costs, the defined cost object makes a difference in defining the category. When the cost object is the payer account, the Payer FTE cost is a fixed cost since each account

requires personnel to manage it. However, for Genentech's legacy product as a whole, the Payer FTE cost would be considered a step-variable cost because the cost is only incurred for every new account added. Therefore it is important to first determine the cost object and then ensure that costs are categorized relative to the cost object.

4.2 Allocating Costs

In order to determine the profitability of individual accounts, indirect costs need to be allocated to each payer account. There are various ways this can be done. This section describes an approach to allocating indirect costs and presents a framework for determining distribution costs.

4.2.1 Allocating Indirect Costs

The traditional method for allocating costs is based on volume – that is, taking total fixed costs and dividing it by the total number of accounts in order to give each account an equal share of the fixed costs. This method may not accurately reflect the consumption of resources, however, as accounts vary in size and may not use equal shares of the fixed cost. For cases such as Genentech's legacy product where there are multiple accounts with large differences in volume and varying discounts, the cost system should be refined to allocate costs based on the activity which drives that cost. The indirect costs in the above categories or cost pools are allocated based on the most applicable *allocation base*. The allocation base is the activity that best approximates how the indirect cost is consumed, such as direct labor hours or number of vials. The fixed costs are then assigned to each account based on an *allocation rate*, such as \$/direct labor hour, or \$/vial.

Allocating costs for payer account FTE

First the payer account FTE cost is allocated. There are a number of supervisors required to manage the payer accounts. There is not necessarily one supervisor assigned to one account, but one supervisor may manage several accounts. It would be insufficient to use the number of accounts as the allocation base and take the total number of FTEs and divide it by the total number of accounts. This assumes that each account requires the same level of attention. In fact some accounts, such as large national accounts may require more coordination and service, while smaller regional accounts might require less. The most appropriate allocation base for this situation is labor hours. For example, if each supervisor works 40 hours a week and 50 weeks a year at \$100K per year, the allocation rate would be \$50/hour. If that supervisor spent 500 hours that year managing

the account for Payer X for Genentech's legacy product, then \$25,000 of the total FTE cost that year would be allocated to Payer X.

An important aspect to note is that the allocation rate is calculated based on the total capacity rather than the total number of hours spent managing the accounts. For example, if the supervisor spent 1800 hours managing accounts for Payer X, Y and Z, and the other 200 hours in training and vacation, it would be misleading to calculate the allocation rate as $\$100\text{K}/1800 \text{ hours} = \$55.55/\text{hour}$. At 500 hours for Payer X, this would allocate \$27,770 to Payer X – the fixed cost for Payer X just increased by \$2,770 without any change to Payer X. This misallocation of costs can result in one of the worst outcomes of faulty accounting, called the death spiral³⁴. Assume that the company no longer contracted with Payer Y and therefore the supervisor spent 1200 hours managing only Payer X and Payer Z. A new incorrect allocation rate of $\$100\text{K}/1200 \text{ hours} = \$83.33/\text{hour}$ would lead to \$4,170 of fixed costs being allocated to Payer X. It appears that Payer X is becoming more expensive to manage. Suppose it became no longer cost effective to manage Payer X and the company no longer contracted with that account, a new allocating rate would be calculated for Payer Z, revealing Payer Z as more costly to manage and this process could continue until the company no longer managed any accounts.

Allocating costs for other overhead

The cost pool of other overhead costs is the portion of shared services (manufacturing overhead, sales and marketing, etc.) among all of Genentech's drugs that is allocated to Genentech's legacy product. The vial volume most closely represents the cost driver for this overhead and therefore is used as the allocation base. The budgeted dollar amount of the cost pool is divided by the budgeted year's volume. An allocation rate of \$/vial is applied to each payer account based on actual volume for that period. With biopharmaceuticals, production is relatively level throughout the year but for seasonal products it is important to ensure that the allocation rate is based on a long time frame such as a year, so that the rate does not vary from month to month as volume fluctuates.

4.2.2 Framework for Determining Distribution Costs

The last cost pools to allocate are those for distribution costs. Since this process is more complex, a framework is presented in order to calculate these costs. As shown in the biopharmaceutical supply

³⁴ (Zimmerman, 2006)

chain (Figure 1), there are two cost flows originating from the manufacturer – one to the payer and one to the distributor. As a vial reaches the patient, it will incur a cost from both the applicable payer and distributor. From the viewpoint of the payer account as the cost object, the distribution cost is then a function of the distributor which is used by that payer for that vial. Thus this process of allocating distributor costs requires understanding the network used for the patient to receive the product, the total discount offered to the distributor and then linking that distributor to the payer. The framework used to accomplish this is shown in Figure 9 and is described below.

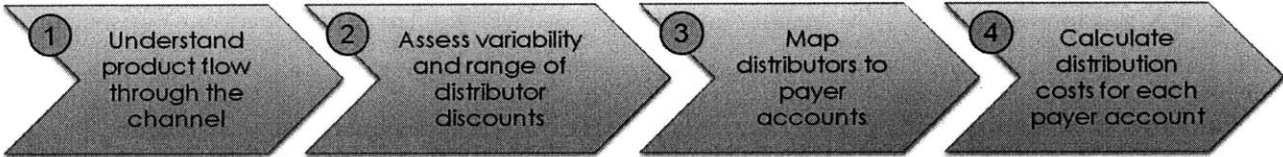


Figure 9: Framework to calculate distribution costs

Step 1: Understand product flow through the channel

A wide variety of distribution models can be employed based on the type of product and the preference of the drug manufacturer. The type of distribution model used will determine how complex the distribution network is and the detail of information available. As Figure 10 shows, these models can range from exclusive networks to open models.

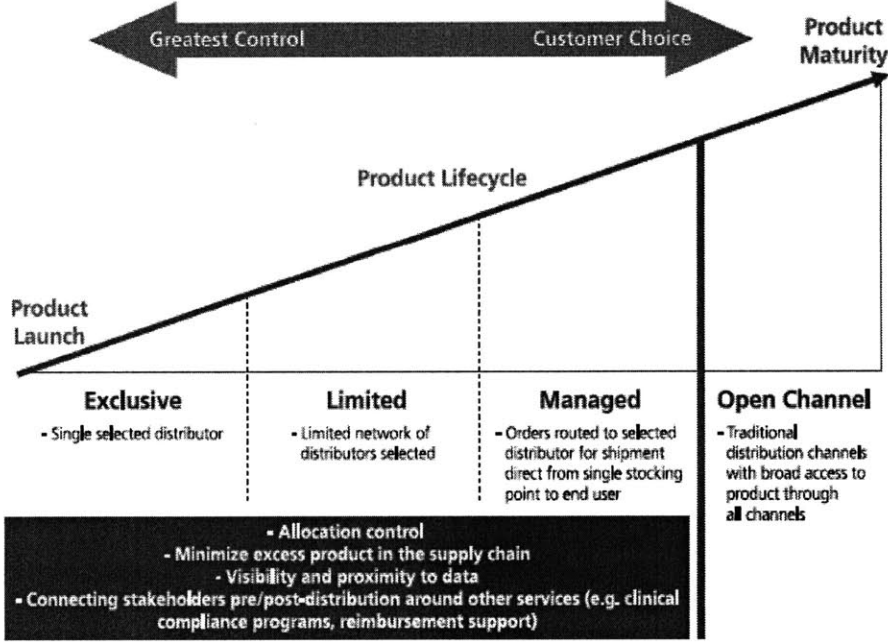


Figure 10: Types of distribution strategies (Bolger, 2009)

At the far left end of the diagram, distribution costs are the easiest to calculate since there is only one distributor and therefore data capture is very precise. As the distribution model moves towards the right side of the diagram, the number and types of distributors increase and so does the range and variability of discounts. Rather than use a single specialty pharmacy, for example, the drug manufacturer might employ various wholesalers, retail pharmacies and specialty distributors. Each entity in turn may ship the product to another distributor and as the number of layers increase between the manufacturer and the patient, data capture becomes more difficult. Furthermore, if discounts are offered to each distributor, the possibility of paying discounts multiple times to different entities for the shipment of the same vial becomes a concern. Therefore, the first step to understanding distribution costs is to understand the product flow. This will enable the drug manufacturer to determine the extent to which each type of distributor is used as well as the type of data that is available.

Step 2: Assess variability and range of distributor discounts

Distributor discounts come in various forms in order to serve different purposes. Across the different distributors there may be a variety of prompt pay discounts, market share or flat rebates, direct discounts, etc. These price concessions may be paid across different time frames, such as a discount off of invoice price, or a rebate paid several quarters later. Due to the variety of the payment data, it is possible that the information is located in different databases within the company or managed by different subunits. In order to accurately evaluate the distribution costs, this step compiles a list of all the distributors used by the product and consolidates the various discounts into variable and fixed costs. Doing this provides a picture of the total effective discount given to each distributor (Figure 11).

Distributor	Variable costs (%)					Fixed costs (\$)			TOTAL (\$)
	Prompt Pay	Market share rebate	Flat rebate	Direct Discount	Total (%)	Data Fee	Nursing Service Fee	Admin Fee	
Wholesaler A	2.0%				2.0%	\$ 12,000			\$ 12,000
..... etc.									
Wholesaler Z	2.0%		3.0%		5.0%	\$ 16,000			\$ 16,000
Specialty Pharmacy AA	2.0%	7.0%	6.0%		15.0%	\$ 3,000	\$ 15,000		\$ 18,000
Specialty Pharmacy BB	2.0%			10.0%	12.0%			\$ 3,800	\$ 3,800

Figure 11: Example spreadsheet of distributor accounts and total discounts and fees

Step 3: Map distributors to payer accounts

Since profits are calculated from the standpoint of a particular payer account, it is necessary to determine the distributors used by each payer account and the percent volume attributed to each one. As shown previously in Figure 7, payers may use only a few distributors or a large network of distributors, but this decision process is made largely independent of the drug manufacturer. Payers often publicize their preferred pharmacies but simply knowing the pharmacy but not the percent volume attributed to each does not provide enough detail to be able to allocate distribution costs to payer accounts. Examining available data, however, it was found that it is possible to link every vial from a distributor to a payer through the use of unique pharmacy identifiers assigned to each vial. The result provides a detailed picture of the distribution composition of each payer and enables one to calculate the attributed distribution costs. Figure 12 shows the distributor composition for three different payer accounts, with different colors for different distributors. The distributors for each payer varies widely – whereas Payer Y uses predominately one distributor and Payer X uses only two, Payer Z uses a large network of distributors. This is as expected because although a payer may prefer to use a certain pharmacy, there may be state and other limitations which affect the extent to which the payer is able to choose the pharmacy, thereby increasing its pharmacy network.

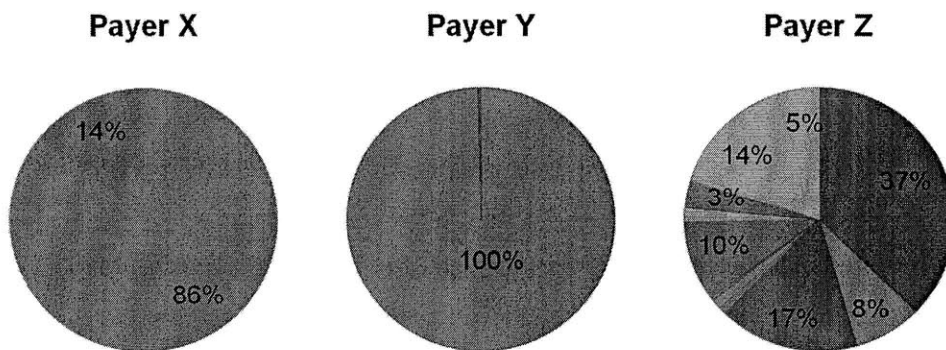


Figure 12: Distribution composition of three payer accounts

Step 4: Calculate distribution costs for each payer account

Once the total discount and costs are determined for each distributor and the distributor can be linked to a payer account, the distribution costs can be allocated to each payer account based on the distribution composition of each payer account. The three cost pools that need to be allocated are average distribution discounts, distributor FTE costs and distributor service fees. Distribution discounts are based on the percent discount for the distributor and the payer composition. For

Payer X as shown above, two distributors are used – Specialty Pharmacy AA and Specialty Pharmacy BB. Respectively they make up 14% and 86% of Payer X’s total volume, and are given discounts of 15% and 11%. Therefore, the distribution discount for Payer X would be 11.6%:

	<u>Payer composition</u>		<u>Total discount</u>		
Specialty Pharmacy AA	14%		15%	=	2.1%
Specialty Pharmacy BB	86%	×	11%	=	<u>9.5%</u>
Average distribution discount of Payer X:					11.6%

The distributor FTE costs are allocated via a two step allocation process where the FTE cost is allocated for each distributor account in the same manner that the payer FTE cost was determined for each payer account previously. Once a dollar amount is determined for the distributor account, it is allocated in the same manner that the other overhead costs were allocated previously, but dividing that amount by the budgeted number of vials to obtain \$/vial. That amount is then allocated to each payer account based on the number of vials it has associated with that distributor. The distributor service fees are determined by dividing the total service fee amount by the budgeted volume of the distributor to obtain \$/vial amount and once again allocated to each payer account based on the volume from that distributor.

4.3 Analyzing Account Profitability

Calculating the costs enables us to determine if the account is profitable on three levels, gives us insight into the distribution of costs for each account, and informs us of the distribution of profitability among accounts.

4.3.1 Account Profitability Concepts

When analyzing the profitability of the account one can look at three different levels of profitability: the contribution margin, account level operating income, and total account operating income, defined as the following:

$$\text{Contribution margin} = \text{Total revenue} - \text{Total variable cost}$$

$$\text{Account level operating income} = \text{Total revenue} - \text{Total variable cost} - \text{Account level fixed costs}$$

$$\text{Total account operating income} = \text{Total revenue} - \text{Total variable cost} - \text{Total fixed costs}$$

Gross revenue	\$ 500,000
<u>Variable costs:</u>	
Contracted payer discount (40%)	\$ 200,000
Average distribution discount (10%)	\$ 50,000
Variable production (5%)	\$ 25,000
Variable marketing and sales (3%)	<u>\$ 15,000</u>
Contribution Margin	\$ 210,000
Contribution Margin (%)	42.0%
<u>Account fixed costs:</u>	
Distributor FTE	\$ 25,000
Distributor service fees	\$ 2,000
Payer account FTE	<u>\$ 50,000</u>
Account Level Operating Income	\$ 133,000
<u>Product fixed costs:</u>	
Other overhead (Marketing and Sales, Production, R&D)	<u>\$ 80,000</u>
Total Account Operating Income	<u>\$ 53,000</u>
Total Account Operating Income (%)	10.6%

Figure 13: Sample ledger for a payer account

An example of these concepts applied to a payer account is shown in

Figure 13. The contribution margin is a measure of the incremental profit gained by the sale of each additional vial to that payer account and informs if at the very basic level the vial is profitable or if one is selling the vial at a loss. If the vial is profitable, each additional sale will generate more profits. The contribution margin is typically high for the biopharmaceutical industry and is applied towards covering fixed costs. The account level operating income is an indication of how profitable that individual payer account is and if the contribution margin is able to cover for all the fixed costs of operating that account. The total account operating income is an indication of whether the contribution margin is able to cover not only the fixed costs of that payer account but also the allocated overhead of the company as well. In this sense, the operating income is used for long-run decisions because for the business to be sustainable, not only does each vial need to have a positive contribution, but the company must generate enough volume to recoup fully its fixed costs. If variable profits are able to cover for all fixed costs, the volume of the account is greater than the break-even point:

$$\text{Break-even point} = \text{Fixed costs} / \text{Contribution margin}$$

Understanding these concepts enable one not only to determine if the payer account is profitable on those three levels, but also to evaluate the effects of decisions as the cost structure is altered by offering more or less discounts, by changing fixed costs or increasing volume. These effects are evaluated through cost-volume-profit analysis. Figure 14 provides a visual depiction at a unit (vial) level. At a unit level, the contribution margin is the marginal profit of the vial, while the operating income per vial is the average profit of the vial.

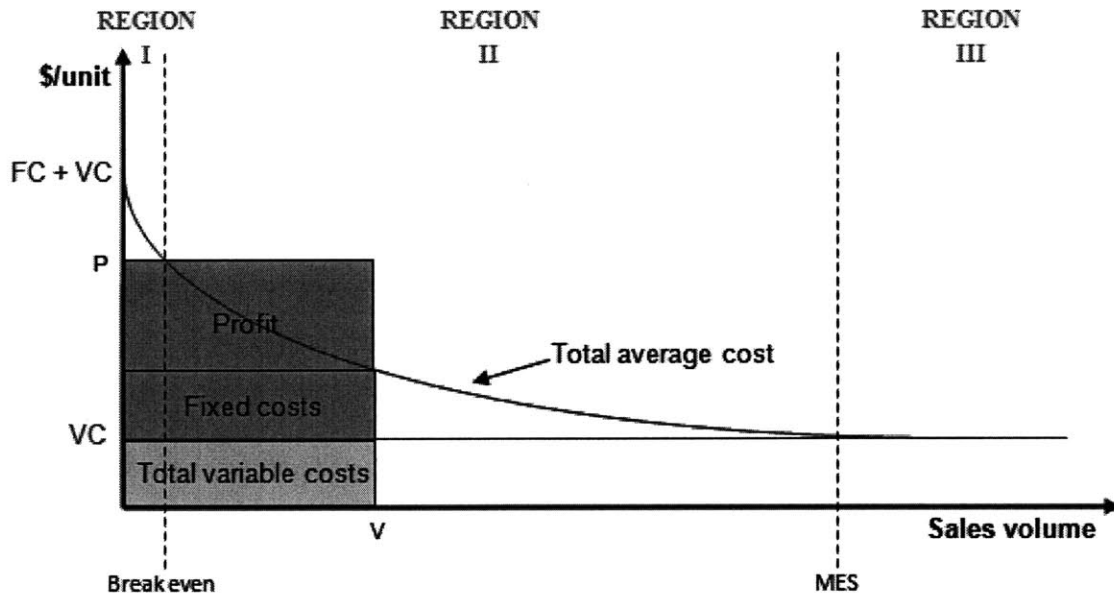


Figure 14: Unit cost behavior

The graph shows a straight line for variable costs (VC) since variable costs are constant relative to sales volume as they are incurred on every unit. The total average cost is the sum of fixed costs (FC) and variable costs and therefore follows a curve that declines per unit of sales volume since average costs are reduced at the vial level as fixed costs are spread over larger and larger volumes. For a given price (P) and volume (V), the account will achieve a total revenue (price x volume), which graphically is the sum of all the rectangles (the areas of profit, fixed costs and variable costs). The profit represented here is the total account operating income. The contribution margin, or marginal profit, is the area of the rectangles for profit and fixed cost (total revenue – total variable cost).

There are three regions in this diagram – Region I highlights accounts below the break-even point. For a given volume at a set price, the account generates negative revenue. Although that account's vials have a positive contribution and each is profitable, the contribution is not enough to pay off

for the account's fixed costs, such as the cost of having personnel managing that account and consequently the account is being operated at a loss.

Above the point of break-even, in Region II, the contribution of the account is enough to cover its fixed costs and the account is profitable. When volume grows to the point where fixed costs are minimized, the minimum efficient scale (MES) is reached and the average cost curve plateaus. MES is more commonly applied to the concept of economies of scale, but is also applicable here to describe the relationship between marginal and average costs. Above the MES, marginal and average costs and hence marginal and average profits are the same since fixed costs are spread over such a large volume to become immaterial, and the cost of each vial becomes only the variable cost.

An understanding of these concepts draws several conclusions for informing business decisions. First, when deciding whether to contract with a new account, it is important to consider the expected volume of that account. Perhaps it may seem favorable to contract with a payer account because the drug manufacturer would be able to negotiate for small discounts which results in a high contribution margin. Every vial would be very profitable. Considering cost-volume-profit trade-offs, however, if the payer account is so small that it is not able to generate enough volume for the contribution to cover all the fixed cost, the account would be operated at a loss. Or if the volume is so low that the resulting profits are small, it may in fact be a better decision for the drug manufacturer to offer a higher discount to contract with an account in Region III rather than offer a lower discount to contract with an account in Region II.

The second conclusion is that discounting has a large impact for high volume accounts because the discount is seen over many vials. For an account in Region III, where the vial costs are essentially only variable costs, at a given price with increasing volume the width of the profit rectangle will increase while the height remains the same. Increasing the discount even only slightly will raise the VC line and decrease profits by the same amount. The area of the profit lost can be a substantial amount, potentially even as much as the total profit of a small account. Before increasing discounts, therefore, one should consider whether volume will also increase comparably to maintain or increase future profits.

4.3.2 Distribution of Costs

Not only does the allocation of costs provide accurate information about account profitability, but it also gives a detailed picture of the cost structure for each account which is not available when simply averaging costs across accounts. Figure 15 shows the cost structure of the variable costs for the sample payer account in

Figure 13. The sum of the contribution margin and total costs is the gross revenue.

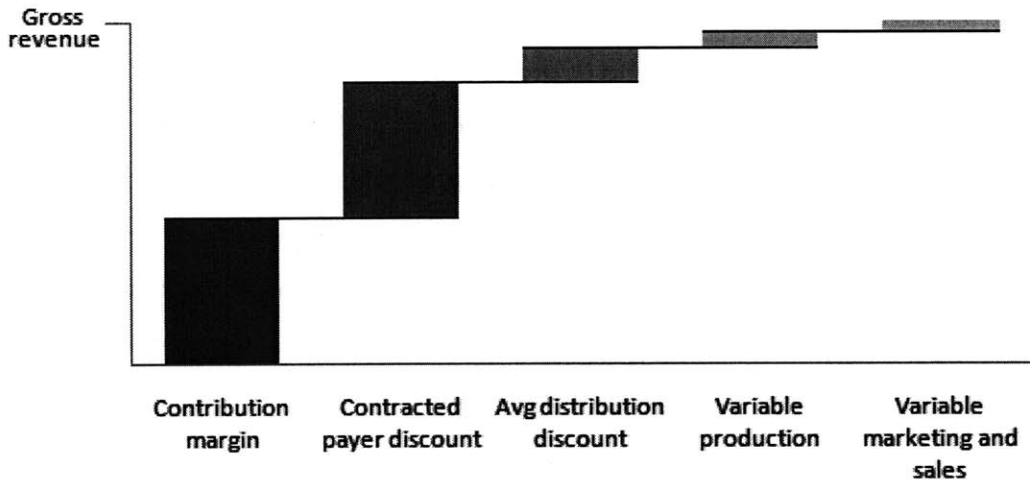


Figure 15: Cost structure of variable costs of a payer account

The cost structure provides information about the sources of costs and relative amount of each. One can see that the largest cost is from the contract payer discount. Knowing this enables one to best direct resources so that focus is on the area which would have the greatest impact. In this scenario, if one lowers the contracted discount by 1% with no impact on volume, the cost savings would be equivalent to a 13% improvement in variable production costs. Understanding the cost structure enables one to evaluate these tradeoffs and know where to best direct efforts.

Understanding the true cost of each vial for the payer accounts also aligns incentives. When costs are averaged across all vials, vials appear to be equally profitable. If the sales force is compensated based on volume, they may be incentivized to offer large discounts in order to increase sales volume and the sales personnel with the largest volume would be rewarded the greatest. Conducting a cost-volume-profit analysis will show that this higher discount is either profitable or possibly not profitable. Knowing the true profit of each vial, however, would enable one to make this evaluation prior to offering the discount to ensure that the result would be profitable. Knowing the true profit

also enables one to refine the compensation structure to base it on profits and not just volume in order to drive the right behavior since profits and not just volume is the desired outcome.

4.3.3 Distribution of Profitability among Accounts

Finally, knowing the profitability of each account provides insight to the relative contribution of each account to the business. As was described earlier, there are cases where the profitable accounts are actually subsidizing the unprofitable accounts because costs are not accurately allocated and the wrong criterion is used to evaluate key accounts. Once the profitability of each account is determined, one can analyze the distribution of profits among accounts graphically by using a cumulative customer contribution analysis curve, also known as the whale curve³⁵. In this curve, accounts are ordered from most profitable to the least profitable and their profits are plotted as a fraction of total profits. If all accounts are equally profitable and every account is profitable, the graph would be a positive linear function. When profitable accounts are subsidizing unprofitable accounts, the curve will cross the cumulative 100% profitability line and then curve back down as unprofitable accounts are added to the curve, as is shown in Figure 16.

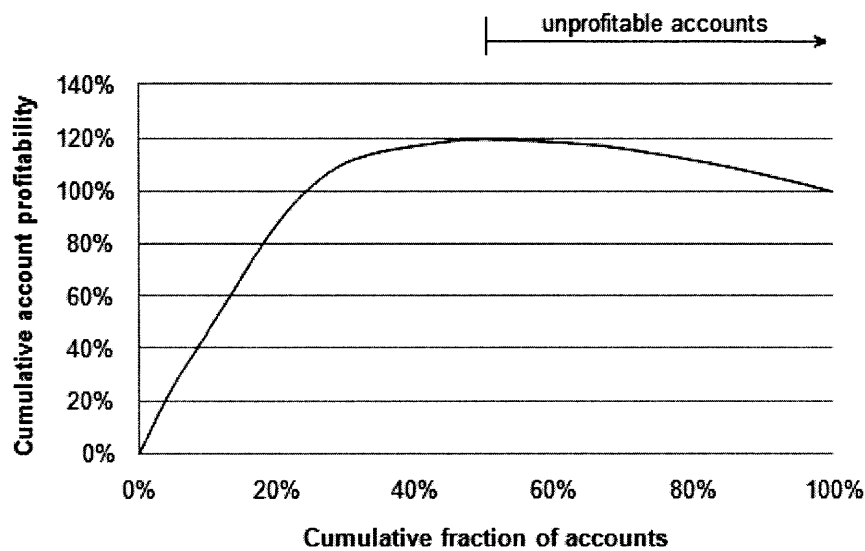


Figure 16: Whale curve exhibiting subsidizing among accounts

The area under the curve between the 100% line and the curve is an indication of the degree of subsidy, with a larger area indicating a larger amount of subsidizing. The shape also indicates the

³⁵ (Kaplan & Cooper, 1998)

relative profitability of the accounts and the vulnerability of the firm. Figure 17 displays four possible combinations of subsidizing and firm dependence, with all four graphs depicting equally profitable firms³⁶.

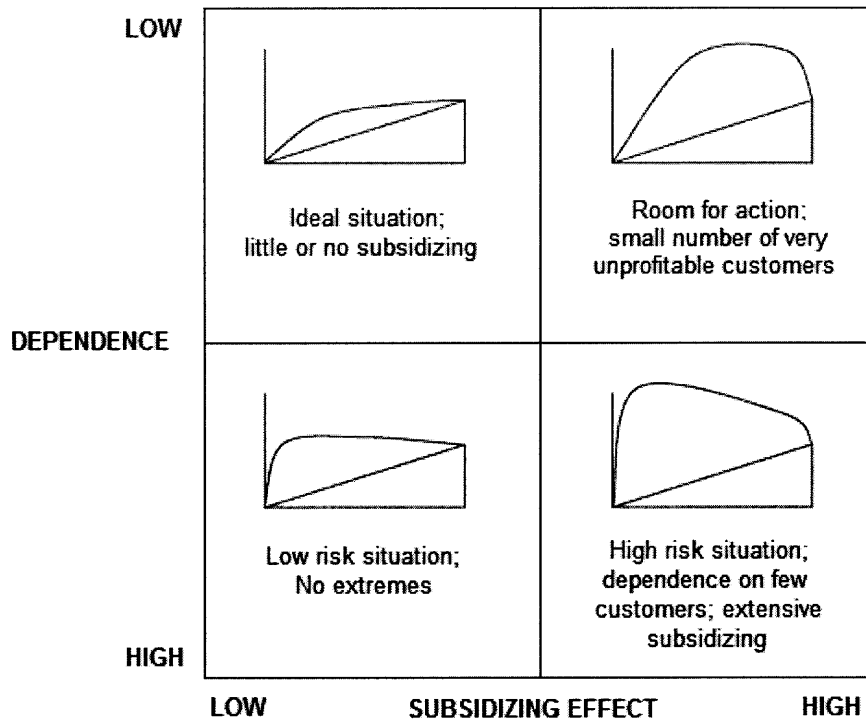


Figure 17: Whale curves for varying levels of subsidizing and dependence (Van Raaij et al., 2003)

The ideal situation is where all accounts have a positive contribution to the business and profits are spread out across accounts. In this case the company is not dependent on a single customer or few customers and therefore its risk is minimized.

The skewness of the curve indicates the level of dependency. The more skewed the curve is to the left, the greater the dependence on a select few customers and the higher the risk since the departure of just one of the profitable customers would result in a large impact to profits for the company.

The more linear the curve becomes, the more evenly spread out are the profits. The concavity of the curve indicates the level of subsidy. A concave curve indicates that some profitable accounts are subsidizing the unprofitable accounts. The sharper the drop at the tail end, the more contained and the higher the unprofitability to a few accounts. This is the case in the figure where there is room

³⁶ (Van Raaij, Vernooij, & Van Triest, 2003)

for action – the sharp drop-off at the tail end of the curve indicates that a few customers are very unprofitable. By changing the cost structure of those customers or if necessary, eliminating those customers, the company can make a large difference towards total profits. The highest risk situation is where there is a high level of skewness with large concavity, which indicates that the company only has a small proportion of profitable customers. The loss of those customers would greatly impact the profitability of the company, but the company’s dependency on them gives them more buyer power, allowing them to negotiate for better terms, which would result in them becoming less profitable³⁷.

4.4 Chapter Summary

Determining actual profits for each account based on a correct cost allocation system provides valuable insights about account profitability. The results show if the account is profitable both at the vial level and account level based on the contribution margin and operating income. An understanding of the distribution of costs gives clarity on where to best direct resources and where the greatest impact can be made in lowering costs. Understanding true profits of each vial also aligns incentives so that cost-volume-profit tradeoffs can be made and decisions can be based on profitability. Lastly, the distribution of profits among accounts can be analyzed to understand if subsidizing is taking place and the level of vulnerability of the company. Together these insights enable better business decisions aligned towards long-term profitability.

³⁷ (Krakhmal, 2006)

5 Creating Tools for Effective Decision Making

This chapter describes the tools created to meet the needs of the organization in the context of managing for profitability.

5.1 Marginal Profit Tool

As it has been discussed, for certain drugs payers will negotiate with drug manufacturers for price concessions in return for directing drug utilization and a preferred formulary position. This is most common in competitive and therapeutically equivalent areas where there are multiple drugs available to treat the same disease. To assist in this contract and negotiation process at Genentech, the marginal profit tool was created (Figure 18).

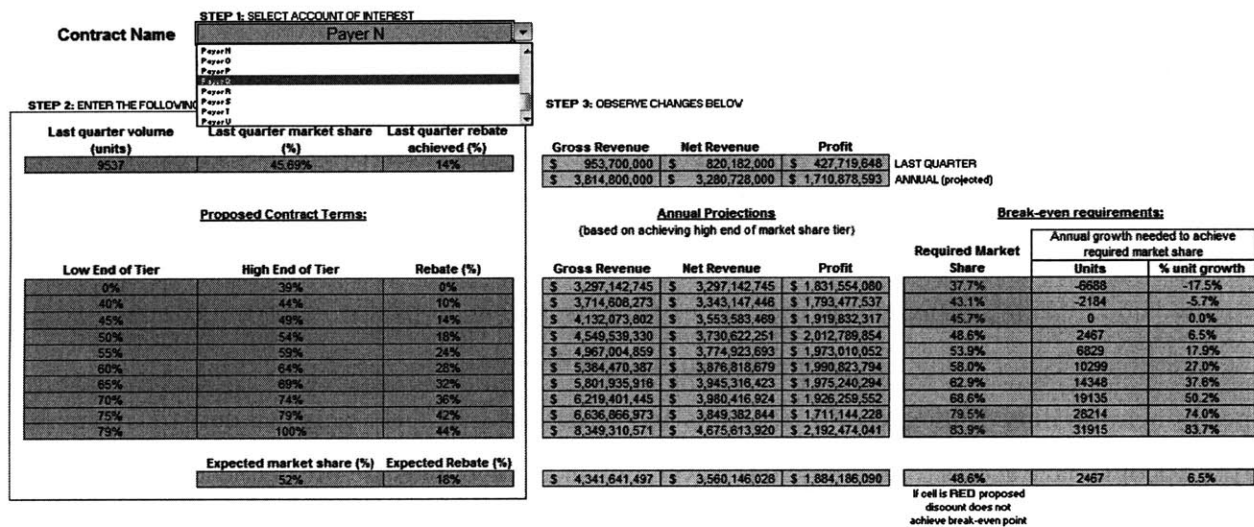


Figure 18: Account specific marginal profit tool

This tool enhances business decisions by enabling the user to evaluate the impact of different scenarios on profitability, by providing an objective output, and by aligning different cross-functional groups.

Evaluating different scenarios for profitability

Every account has a different cost structure as shown in the calculations performed in the previous chapter. As a result, discounting decisions affect profits in different ways for different accounts. The person managing the payer account needs to be able to evaluate cost-volume-profit tradeoffs, prior-to and during negotiations, but has limited access to the information required to make a these

decisions. It is difficult if not impossible for an account manager to collect all the information necessary to determine the contribution margin and operating income of that account. The process of cost allocation is not something that is performed at that level but its outcome provides information that the account manager needs to make an informed decision on profitability. If the reservation value is not known, discounts could potentially be offered resulting in a negative profit.

The marginal profit tool consolidates the cost information for every account, with each account's unique cost curve. By selecting the desired account from a drop-down menu, the account manager can evaluate the impact on gross revenue, net revenue and profits for different discounting scenarios. The tool also displays the necessary change in volume for a higher discount to ensure that profits are maintained or increased, as the system dynamics model showed that profits would lower if the increase in volume is not comparable to the increased discount.

Providing an objective output

Aside from providing an effective way to evaluate individual accounts, the tool also provides an objective output. If people are intent on getting the drug to the patient, winning a contract bid, or increasing sales volume, these motivations can bias decisions. At Genentech people are very patient focused and making a difference in the lives of patients is a big motivator. Losing a contract bid can be interpreted as not doing the company's part in ensuring patient access to the drug. Field personnel who directly interact with accounts and physicians may feel a personal duty to ensure that those people have access to the drug. However, not all contract bids are profitable and in order for the business to continue its purpose in serving patients in the long-run, it must base decisions on long-term sustainability. Genentech's tag line used to be "In Business for Life" which summarizes its passion for patients. But as it once stated in its annual financial report, "to continue to be in business for life, Genentech must also be in business for results."³⁸ Removing subjectivity from the decision-making process enables decisions to be made based on profitability in an objective manner.

Aligning cross-functional groups

Lastly, the tool aligns different cross-functional groups. The process of contract negotiations and the determination of discount terms require the interaction of people from the corporate office with people on the field to ensure that goals are realistic and attainable. The tool performs a cost-

³⁸ Genentech 1998 annual report

volume-profit analysis to determine the required sales volume for profitability based on different contracting discounts. By incorporating understanding of these profitability requirements, the tool provides a basis for different groups to cohesively decide whether the output is reasonably achievable or if discount terms need to be modified.

5.2 Payer Account Dashboard

Companies receive a variety of information which provides feedback regarding product performance, and based on the difference between perceived and desired performance, they may adjust actions in order to close the gap between the two. While the marginal profit tool is an interactive tool which assists decisions based on profitability, the payer dashboard consolidates data from many different locations to provide an effective means for monitoring product performance.

The company periodically receives information about product market share, gross revenue, net revenue and profits, but as the system dynamics model demonstrates, these performance indicators are the result of interactions among many dynamic variables. Therefore decisions need to be made based on an holistic understanding of the dynamics of that account. Rarely, however, is information for an account found in one location and in a manner which enables quick and easy analysis. Furthermore among accounts there is a large variation in the level of discounts and volume. Plotting Genentech's legacy product on a cumulative profitability curve shows that there is a large difference in contribution across different accounts. Therefore not only is it beneficial to be able to evaluate the performance of a single account, but also to be able to compare the relative performance across accounts. The payer dashboard was designed with these objectives in mind.

Figure 19 is an illustration of one section of the dashboard. The dashboard provides consolidated information in one location for all of the commercial payer accounts. One can evaluate several aspects of account performance using the dashboard, including relative performance and trends.

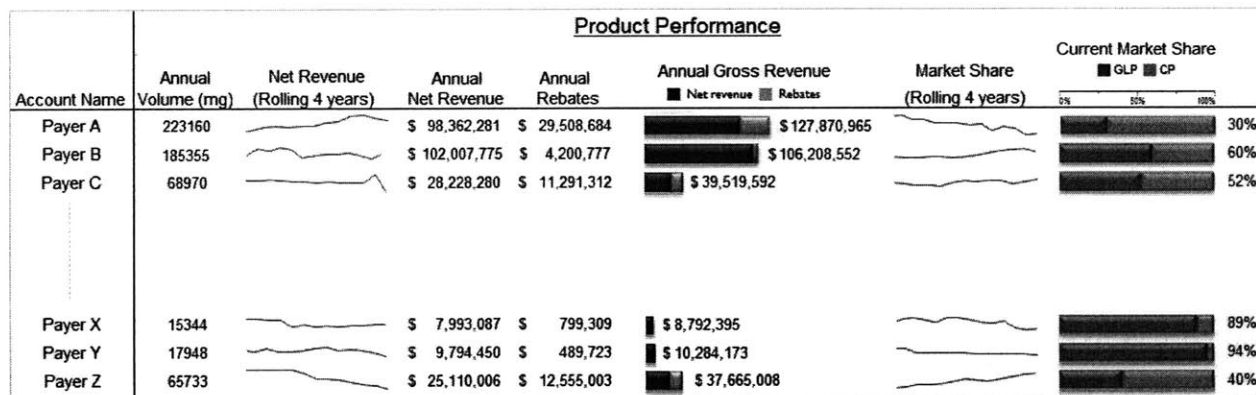


Figure 19: Payer account dashboard

Relative performance

The dashboard graphically displays account performance, making it visually easy to see which accounts have the greatest impact to the company. Observe that Payer A and B have several times the net revenue of Payer X and Y. One can also compare the performance of Payer A to Payer B and see that although Payer A has a higher volume and gross revenue, due to its higher discounting Payer B actually has higher net revenue. Payer X and Y have a much smaller discount percentage than most of the other accounts, but due to their small size their resulting revenue is quite small. Observing market share one sees that Payer X and Y are small accounts but have very high market share and therefore there is little room for revenue to grow. The account will continue to have a small impact on revenues unless the actual number of patients in that account increases. Presenting account information in one location, side-by-side for different accounts, enables the user to evaluate relative account performance and easily determine the impact of each account to the business.

Trends

The dashboard also displays trends, which enables one to evaluate performance for an account over a period of time. The graphical representation allows for easier analysis rather than looking at numbers across a spreadsheet. Presenting trends for two variables in one location allows for comparisons to be made between net revenue and market share. Analyzing net revenue trends for each account, one can notice a substantial drop in net revenue for Payer C. Comparing net revenue trends to market share trends one observes that Payer Z's net revenue is decreasing while its market share is increasing. This observation may lead to further analysis which shows that the discounting for Payer Z is increasing at a rate faster than the volume growth. If one evaluated these two variables in isolation one may not have been able to see this relationship between the two and make

that conclusion. Evaluating Payer A one notices that the opposite is occurring – net revenue is rising but market share is decreasing. Further analysis may reveal that the Payer A has been making small acquisitions over the years and therefore account size has been increasing over time as new patients join that plan. The number of patients using the product is increasing, but not as fast as the growth of the account. As a result, net revenue is increasing but market share is decreasing. If one evaluated net revenue trends alone, one may have drawn an inaccurate conclusion that Payer A's performance has been improving over the years.

Consolidating information in one location in the form of a dashboard enables users to effectively evaluate account performance. Data may be located in various databases, spreadsheets and shared drives but by aggregating it in a visual form, decision makers can determine relative account performance in an efficient manner and draw conclusions about individual account performance, obtaining insights which otherwise may have been missed.

6 Conclusion

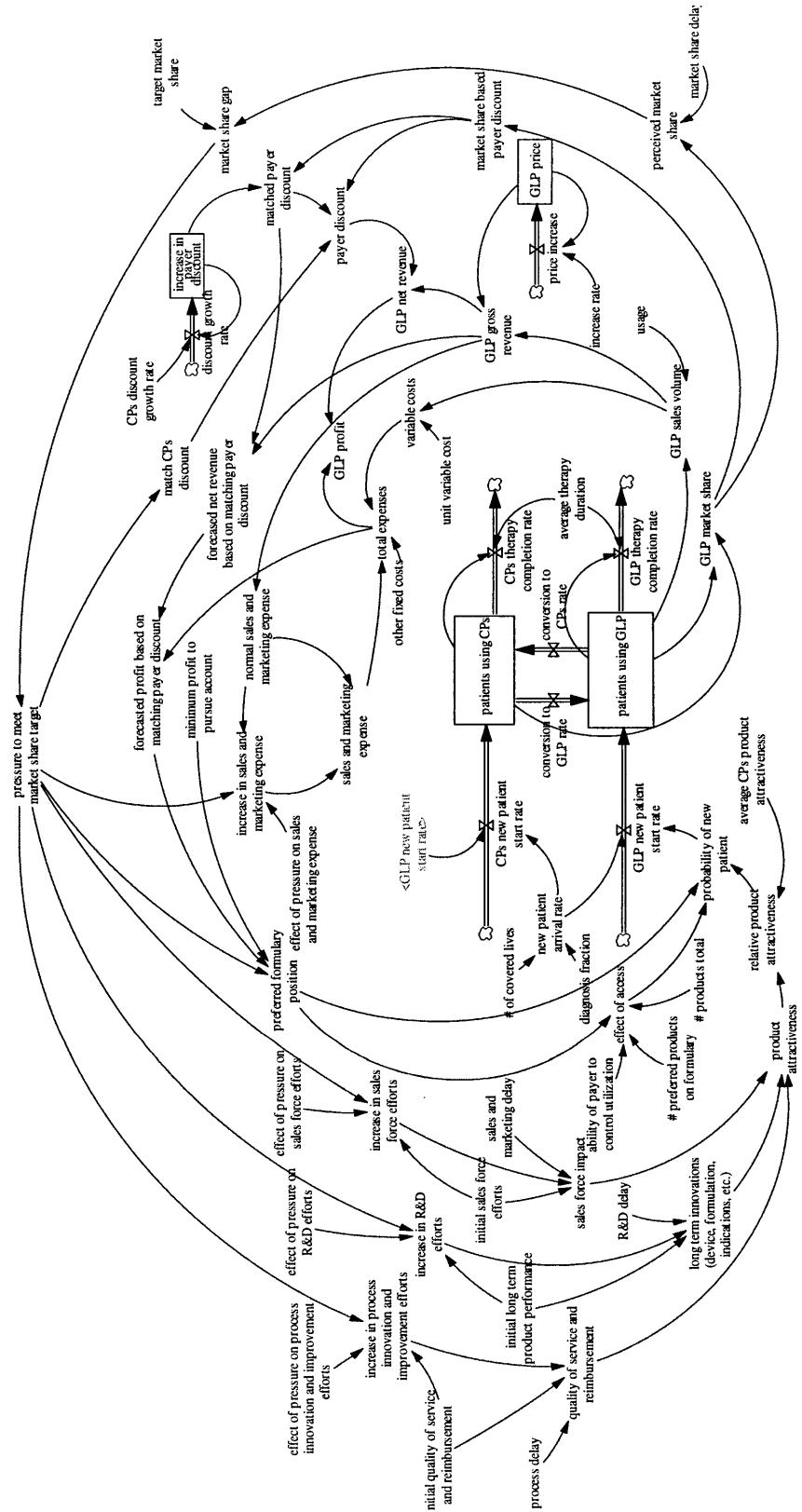
Using Genentech's legacy product as a case study in understanding profitability in the context of a competitive environment has facilitated better business decision making. The nature and resulting effects of competition require a different way of approaching profitability. Through system dynamics modeling one sees that due to price competition and increased discounting, profits may no longer follow market share and gross revenue. This leads to a need to understand account level profits. Account level profits, however, actually become more difficult to determine in a competitive environment, largely due to the greater variability in discounts and the increased level of account management and service costs which necessitate activity based costing to accurately allocate costs.

In this study a framework as well as an approach is introduced to determine account level profitability and to calculate distribution costs in the context of the biopharmaceutical industry. Understanding account level profits not only informs if the account is profitable, but provides invaluable information in knowing the magnitude of costs to determine where best to allocate resources. It also informs the distribution of profitability across accounts thereby indicating subsidy and vulnerability, and enables compensation programs to be fine-tuned to promote profitable decisions.

Aside from providing key insights, the results of this analysis have impacted Genentech in actionable ways. The sales compensation structure is being modified in order to incentivize decisions based on profit rather than on the traditional measure of volume. An analysis of labor hours is being performed to better understand the actual resource requirements for different accounts which will improve the understanding of capacity requirements and also result in a more accurate allocation of FTE costs. Tools such as the marginal profit tool and the dashboard are actively in use to assist in making profitable decisions in the future. Lastly, this study is in the process of being applied to other Genentech products as well for which the topic is relevant. By understanding profitability in a competitive environment, Genentech will be more equipped to make long-term sustainable decisions. The results will not only benefit the company but better the industry as a whole.

Appendices

Full System Dynamics Model



System Dynamics Model Equations

- (01) "# of covered lives"=
Units: patient
- (02) "# preferred products on formulary"=
Units: Dmnl
- (03) "# products total"=
Units: Dmnl
- (04) ability of payer to control utilization=
Units: Dmnl
Range 0-1, 1=high, 0=low
- (05) average CPs product attractiveness=
Units: Dmnl
Scale from 0-100
- (06) average therapy duration=
Units: Year
- (07) conversion to CPs rate=
Units: patient/Year
- (08) conversion to GLP rate=
Units: patient/Year
- (09) CPs discount growth rate=
Units: 1/Year
- (10) CPs new patient start rate=new patient arrival rate-GLP new patient start rate
Units: patient/Year
- (11) CPs therapy completion rate=patients using CPs/average therapy duration
Units: patient/Year
- (12) diagnosis fraction=
Units: 1/Year
- (13) discount growth rate=IF THEN ELSE(increase in payer discount>0.8 , 0 , CPs discount growth rate)
Units: 1/Year
- (14) effect of access=1/("# products total"-ability of payer to control utilization*(ABS("# products total"- "# preferred products on formulary")))*preferred formulary position
Units: Dmnl
Range 0-1
- (15) effect of pressure on process innovation and improvement efforts=
Units: Dmnl
- (16) effect of pressure on R&D efforts=
Units: Dmnl
- (17) effect of pressure on sales and marketing expense=
Units: Dmnl
- (18) effect of pressure on sales force efforts=
Units: Dmnl
- (19) FINAL TIME = 4
Units: Year
The final time for the simulation.
- (20) forecasted net revenue based on matching payer discount=GLP gross revenue*(1-matched payer discount)

- Units: \$
- (21) forecasted profit based on matching payer discount=forecasted net revenue based on matching payer discount-total expenses
Units: \$
- (22) GLP gross revenue=GLP price*GLP sales volume
Units: \$
- (23) GLP market share=patients using GLP/(patients using GLP+patients using CPs)
Units: Dmnl
- (24) GLP net revenue=GLP gross revenue*(1-payer discount)
Units: \$
- (25) GLP new patient start rate=new patient arrival rate*probability of new patient
Units: patient/Year
- (26) GLP price= INTEG (price increase,100)
Units: \$/mg
- (27) GLP profit=GLP net revenue-total expenses
Units: \$
- (28) GLP sales volume=patients using GLP*usage
Units: mg
- (29) GLP therapy completion rate=patients using GLP/average therapy duration
Units: patient/Year
- (30) increase in payer discount= INTEG (discount growth rate,0)
Units: Dmnl
- (31) increase in process innovation and improvement efforts=initial quality of service and reimbursement*effect of pressure on process innovation and improvement efforts*pressure to meet market share target
Units: Dmnl
- (32) "increase in R&D efforts"=(initial long term product performance*"effect of pressure on R&D efforts"*pressure to meet market share target)
Units: Dmnl
- (33) increase in sales and marketing expense=effect of pressure on sales and marketing expense*normal sales and marketing expense*pressure to meet market share target
Units: \$
- (34) increase in sales force efforts=initial sales force efforts*effect of pressure on sales force efforts*pressure to meet market share target
Units: Dmnl
- (35) increase rate=
Units: 1/Year
- (36) initial long term product performance=
Units: Dmnl
Range 0-30
- (37) initial quality of service and reimbursement=
Units: Dmnl
Range 0-50
- (38) initial sales force efforts=
Units: Dmnl
Range 0-20
- (39) INITIAL TIME = 0
Units: Year

The initial time for the simulation.

- (40) "long term innovations (device, formulation, indications, etc.)"=MIN(30, (initial long term product performance+STEP("increase in R&D efforts", "R&D delay")))
Units: Dmnl
Range 0-30
- (41) market share based payer discount = WITH LOOKUP (GLP market share,(((0,0)-(1,1)],(0,0.1),(0.3,0.1),(0.3,0.14),(0.4,0.14),(0.4,0.18),(0.5,0.18),(0.5,0.22),(0.6,0.22),(0.6,0.26),(0.7,0.26),(0.7,0.3),(1,0.3)))
Units: Dmnl
- (42) market share delay=0.5
Units: Year
- (43) market share gap=target market share-perceived market share
Units: Dmnl
- (44) match CPs discount=IF THEN ELSE(pressure to meet market share target>0, 1, 0)
Units: Dmnl
1=match discount, 0=not match discount
- (45) matched payer discount=market share based payer discount+increase in payer discount
Units: Dmnl
- (46) minimum profit to pursue account=
Units: \$
- (47) new patient arrival rate="# of covered lives"*diagnosis fraction
Units: patient/Year
- (48) normal sales and marketing expense=X*GLP gross revenue
Units: \$
- (49) other fixed costs=
Units: \$
- (50) patients using CPs= INTEG (conversion to CPs rate+CPs new patient start rate-conversion to GLP rate-CPs therapy completion rate,400)
Units: patient
- (51) patients using GLP= INTEG (+conversion to GLP rate+GLP new patient start rate-conversion to CPs rate-GLP therapy completion rate,200)
Units: patient
- (52) payer discount=IF THEN ELSE(match CPs discount=1, matched payer discount , market share based payer discount)
Units: Dmnl
- (53) perceived market share=SMOOTH3(GLP market share,market share delay)
Units: Dmnl
- (54) preferred formulary position=IF THEN ELSE(pressure to meet market share target>0:OR:forecasted profit based on matching payer discount>minimum profit to pursue account,1,0)
Units: Dmnl
1=preferred, 0=non-preferred
- (55) pressure to meet market share target=IF THEN ELSE(market share gap>0,market share gap,0)
Units: Dmnl
- (56) price increase=increase rate*GLP price
Units: \$/(Year*mg)

- (57) probability of new patient=IF THEN ELSE(preferred formulary position=1, (effect of access+relative product attractiveness*(1-effect of access)),(relative product attractiveness*(1-effect of access)))
Units: Dmnl
- (58) process delay=0.75
Units: Year
- (59) product attractiveness="long term innovations (device, formulation, indications, etc.)"+quality of service and reimbursement+sales force impact
Units: Dmnl
Range 0-100
- (60) quality of service and reimbursement=MIN(50, initial quality of service and reimbursement+SMOOTH3(increase in process innovation and improvement efforts, process delay))
Units: Dmnl
Range 0-50
- (61) "R&D delay "=5
Units: Year
- (62) relative product attractiveness = WITH LOOKUP (product attractiveness-average CPs product attractiveness,([(-100,-1)-(100,1)],(-100,-1),(-87,-0.929825),(-75,-0.842105),(-68,-0.754386),(-58,-0.605263),(-50,-0.473684),(-45,-0.350877),(-37,-0.254386),(-28,-0.149123),(-16,-0.0438596),(0,0),(10,0.0350877),(24,0.122807),(37,0.245614),(46,0.412281),(50,0.508772),(59,0.701754),(69,0.859649),(82,0.95614),(100,1)))
Units: Dmnl
- (63) sales and marketing delay=0.75
Units: Year
- (64) sales and marketing expense=normal sales and marketing expense+increase in sales and marketing expense
Units: \$
- (65) sales force impact=MIN(20, (initial sales force efforts+increase in sales force efforts)+SMOOTH3(increase in sales force efforts,sales and marketing delay))
Units: Dmnl
Range 0-20
- (66) SAVEPER = TIME STEP
Units: Year
The frequency with which output is stored.
- (67) target market share=
Units: Dmnl
- (68) TIME STEP = 0.125
Units: Year
The time step for the simulation.
- (69) total expenses=other fixed costs+sales and marketing expense+variable costs
Units: \$
- (70) unit variable cost=
Units: \$/mg
- (71) usage=
Units: mg/patient
- (72) variable costs=unit variable cost*GLP sales volume
Units: \$

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