

# The Pharmaceutical Supply Chain: a Diagnosis of the State-of-the-Art

by

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Submitted to the Engineering Systems Division  
in partial fulfillment of the requirements for the degree of

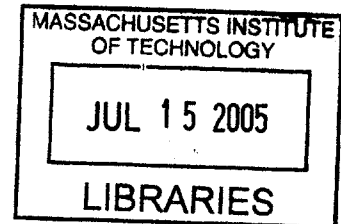
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**BARKER**

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## **Abstract**

This study explores the current supply chain trends in the pharmaceutical industry. The main objective of the study is to characterize the pharmaceutical industry and identify excellent supply chain practices. Indeed, the pharmaceutical industry is not renowned for its supply chain management capabilities, unlike many other highly publicized industries that have profitably exploited their supply chains. It is, thus, an interesting topic for research. A closer look, however, reveals that our initial assessment of the industry is colored by the popular financial criteria prevalent among analysts and the investing public. This research will suggest that the pharmaceutical industry *does* care about its supply chain, although, a reevaluation of the supply chain strategy is necessary for addressing problems effectively. In fact, we will argue that an excellent supply chain is paramount to the pharmaceutical industry's success.

We subscribe to the view that a supply chain should be considered excellent if it is able to effectively support a business strategy. The business objectives of the pharmaceutical industry include the need to ensure that the drugs are protected from adulteration and counterfeiting, removed and destroyed in a safe and environmentally friendly manner, and made available to patients at all time. Clearly, these are not commonly used metrics to assess the performance of a company or a supply chain. Instead, characteristics that have direct impact on the short term financial well being of the company, such as reduced lead times, increased flexibility, and lower cost are the ones that take precedence. As a result, there is a huge gap between the actual and perceived capabilities of the pharmaceutical supply chains. Furthermore, there are clear indications that a radical transformation of the pharmaceutical industry is on the horizon which will require further strengthening of its supply chains, rendering it even more critical to success.

Thesis Supervisor: Charles H. Fine  
Title: Chrysler LFM Professor of Management Science

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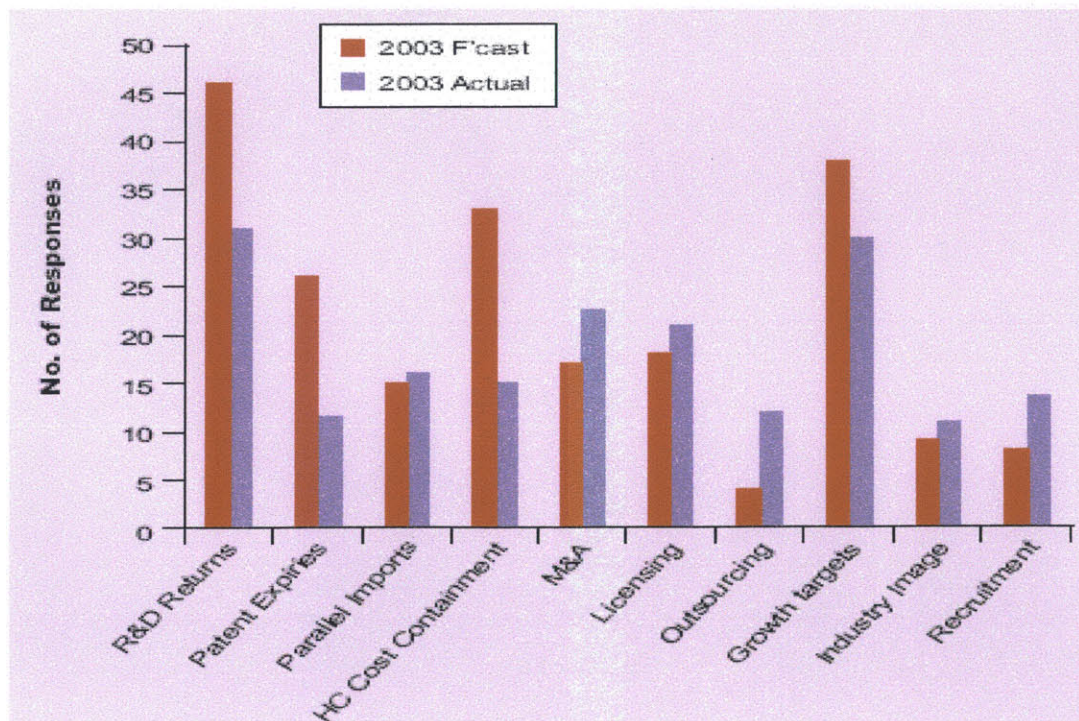
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## Chapter 1: Introduction

The pharmaceutical industry is a complex enterprise fraught with conflicting objectives and numerous intractable constraints. A highly regulated environment coupled with the life altering nature of the products characterizes the pharmaceutical industry as a uniquely difficult system. A preliminary review will suggest that supply chain related issues are not likely to figure among the biggest challenges facing the pharmaceutical industry— see Figure 1.1. For a multi-billion industry that manufactures and distributes products to millions of people every day, failing to notice supply chain issues certainly seems unusual and worth investigating.



Source: Pharmafocus, 20 Apr 2004

Figure 1.1: Most Frequently Cited Pharmaceutical Industry Issues

In contrast, companies such as Dell, Amazon.com, and Wal-Mart have made it to the top purely on the strength of their supply chains. In fact, creative supply chain management solutions and innovations in Information Technology are sweeping the market. An efficient and agile supply chain is now considered essential for developing a sustainable competitive advantage. So, what sets the pharmaceutical industry apart from other sectors in this regard?

Indeed, there are some obvious explanations for the seemingly counterintuitive behavior. It is likely that the pharmaceutical industry's profitable heritage is responsible for its lack of focus on supply chain efficiencies. Another possibility is that the relatively low cost of good sold (COGS) makes it easy for the management to choose a simple minded strategy of buffering all problems with inventory. In other words, it appears that there is little or no impetus to properly address internal company efficiencies in the pharmaceutical industry. So, why should we investigate the pharmaceutical industry supply chain?

### 1.1 Motivation

According to the Supply Chain Council, supply chain management includes managing supply and demand, sourcing raw materials and parts, manufacturing and assembly, warehousing and inventory tracking, order entry and order management, distribution across all channels, and delivery to the customer. Indeed, management and coordination of supply chain is at the core of any industry that manufactures and distributes goods.

At the same time, it is important to realize that supply chains of different industries are dissimilar as they address different needs. For example, in the computer industry, the power of supply chains is harnessed to offer customers product configuration flexibility at a low cost, whereas in the consumer goods industry, the focus is on product variety, availability, and cost. In fact, it can be easily argued that good business performance is predicated on the formation of an efficient supply chain; in progressive organizations, the integration of supply chain management with strategic planning is complete and irreversible.

Being so vital to the success of a business, it is only natural that companies continually seek new ways to configure their supply chains to remain competitive. Now, with the aid of breakthrough progress made in the area of Information Technology, companies are deploying increasingly sophisticated solutions to further improve the efficiency of supply chains. We can only imagine the possibilities that innovative techniques, such as RFID and nanotechnology will open up for designing future supply chains.

To address this very issue of the future of supply chains, the MIT Center for Transportation and Logistics has commissioned a multi year study entitled 'The Supply Chain 2020 (SC2020) Project.' According to the description found on its website, the SC2020 project is a multiyear research effort to identify and analyze the factors that are critical to the success of future supply chains. This pioneering project will map out innovations that underpin successful supply chains as far into

the future as the year 2020. Furthermore, the SC2020 research is broad and far-reaching, and is designed to meet a series of objectives in two phases.

In Phase I, the focus is on understanding excellent supply chains and the underlying strategies, practices, and macro forces that drive them. Specifically, this phase involves identifying and researching the organizations that drive today's successful supply chains in a broad range of industries. The aim is to understand the evolving business strategies, operating models, practices and principles that are responsible for driving improved performance.

In Phase II, knowledge and learning from Phase I will be leveraged to project the future using scenario generation and planning methodologies. The work will highlight the actions that organizations should take to ensure supply chain excellence. For more information, visit the project website at [www.sc2020.net](http://www.sc2020.net).

Pharmaceutical industry is one of the ten industries identified for detailed investigation under Phase I of the SC2020 project. The pharmaceutical industry makes a large contribution to the national GDP and extremely critical to the well being of any nation. It, however, lags other industries in the application of modern supply chain principles and practices. There are some obvious reasons that justify the lack of penetration of the latest techniques in the pharmaceutical industry; however, the working hypothesis of SC2020 research presumes that an excellent supply chain has the following characteristics:

- ☞ supports and enhances the strategy of the business, as well as being an integral part of the overall design of the business.
- ☞ embodies a complementary (not necessarily unique) operating model that creates competitive advantage.
- ☞ emphasizes high-performance execution, where performance is defined by a balanced set of business-relevant objectives or metrics.
- ☞ leverages a tailored (small) set of business practices that support the above. These business practices are consistent, reinforcing, and cross-optimized.

In other words, an excellent supply chain is not limited only to those instances where the resulting benefits include tangible cost savings or other similar measurable metrics popularly tracked by analysts and investing public. It is important to highlight here that excellent practices in business environment may mean a variety of things depending on need and application. Furthermore, strategies providing intangible benefits are often neglected in order to accommodate solutions that generate immediate tangible returns.

## 1.2 The Pharmaceutical Business

“Man has moved up the therapeutic hierarchy, through magic, voodoo, faith healing, to modern, orthodox medicine and surgery.” (Peter and Hill, 1969) We have come a long way from summoning supernatural powers to developing a systematic scientific approach for disease management; from using herbs concocted by the “medicine man”—the first drug maker, to the large modern day industrial units manufacturing complex chemical compounds.

The pharmaceutical industry is thus, as old as mankind. It has evolved over time to thwart the threat of old and new diseases by applying latest knowledge. And the transformation has been spectacular. At the same time, it is important to note that we still haven't conquered "disease," and the jury is still out on how much "real" progress we have made in this area.

In the meantime, parallel developments have also taken place on the business organization side of the pharmaceutical industry, albeit mediocre at best. The recent years have, however, witnessed a violent and noticeable structural reorganization in the pharmaceutical industry including, drug discovery, clinical trials management, drug launch and marketing, production, distribution, and drug delivery mechanisms. To put the recent changes in perspective, it is worth noting that the pharmaceutical industry remained stable up until the early 1990s. In other words, leading companies have maintained their dominance and enjoyed uncontested success for almost a century (Bradley and Weber, 2004).

The stability of pharmaceutical industry is all the more intriguing given the consistent and strong demand for better drugs to improve the quality of life and support rapidly ageing population. In fact, for a long time, the pharmaceutical industry has been one of the most profitable industries (Bradley and Weber, 2004). The pharmaceutical industry appears to be heading for a period of rapid and radical transformations. For example, we can expect to see the rise of new

business models that will move away from the current blockbuster drug model to a model that can support a more stratified personalized medicine space.

It is apparent that the pharmaceutical industry is a big and complex structure that is composed of numerous heterogeneous segments. Indeed, there are numerous ways to segment this market; one typical way is to segment based on the product type, such as branded drugs, generics, OTC etc. Each such segment is peculiar on account of its unique requirements. Another basis of segmentation is the nature of the drug, i.e., a chemical or small molecule drug versus a biologic or large molecule drug.

The segmentation is important since the challenges faced by various categories are significantly different and should have customized supply chains. The problem is made more difficult by the interplay of fundamentally different types of key stakeholders, such as drug manufacturers, wholesale distributors, retail pharmacies, hospitals, managed care organizations, and insurance companies.

### 1.3 Research Scope

In this report, we will examine the state-of-the-art of the pharmaceutical supply chains to identify excellent supply chain characteristics, if any. We will investigate the relationship between key business drivers, supply chain infrastructure, and business practices to assess the effectiveness of the supply chains. Furthermore, we will comment on the ability of supply chain

management techniques to offer sustainable competitive advantage. We will limit the scope of our research to focus solely on the patented small molecule drug (chemicals) segment of the pharmaceutical industry operating in the United States. Consequently, our views will be skewed and not representative of the pharmaceutical industry in general.

#### 1.4 Methodology

We followed a three tiered approach to assess the state-of-the-art of the pharmaceutical supply chains. To begin with, we carried out an extensive search of the published material including trade journals, industry publications etc. to develop an in-depth understanding of the pharmaceutical business by focusing specifically on the supply chain function. To enhance and validate our knowledge, we sought opinions from various industry experts. Lastly, to further substantiate our research, we conducted two separate case studies focusing on supply chain functions at two of the largest companies in the pharmaceutical industry.

In particular, we selected Eli Lilly and Co (NYSE symbol LLY), a drug manufacturer and Cardinal Health Inc (NYSE symbol CAH), a wholesale distributor, to obtain a comprehensive view of their overall supply chain. We interviewed key members belonging to the supply chain organizations of the two companies to establish the ground realities of their respective supply chain operations.



The report is organized as follows. In Chapter 2, a brief literature review of current publications in the academic and trade journals along with industry publications is presented. This is followed by a detailed overview of the pharmaceutical industry in Chapter 3 to give the reader a sense of its enormity and implications on the well being of society. Chapters 4 and 5 consist of case studies describing the practice of supply chain management at two separate companies engaged in manufacturing and distributing drugs. In chapter 6, we use the Excellent Supply Chain Framework proposed by the Supply Chain 2020 project to characterize the pharmaceutical industry. Synthesis and analysis is presented in chapter 7 to highlight some salient aspects of the industry focusing on problems and solutions that are critical to the growth of the pharmaceutical industry. Lastly, chapter 8 presents some conclusions.

## **Chapter 2: Literature Review**

This research looks at a very broad topic of pharmaceutical supply chains.

Specifically, the main objective of this research is to assess the state-of-the-art of the pharmaceutical supply chain to gain a better understanding of the fundamental forces at work. A supplementary but critical objective is to comment on the supply chain practices at two of the largest companies in the pharmaceutical industry.

Indeed, the topic under consideration is an assemblage of numerous subjects and concepts that are big research projects in themselves. To select a subset of publications that will not overlook anything significant presents a difficult challenge. And we make no claim that all important publications have been considered and reviewed in completing this research. Interestingly, after reviewing the available literature, we realized that majority of the publications relevant to our topic belong to the industry/trade domain, only a few publications could be classified as academic research.

Although the publications in the trade journals and business publications offered great insights, most had a business bias to it. In this research, we will try to provide an unbiased opinion on the topic. Based on our assessment of the reviewed literature, we decided to limit our scope and discuss a set of articles that, in our opinion, offered relevant background to this work. These publications are expected to help the reader align our effort with the objective of the research.

To this end, we have divided the review into four main categories dealing with different topics, such as supply chain strategy, general state of the healthcare industry including the pharmaceutical industry, pharmaceutical supply chains, and other important topics.

## 2.1 Supply Chain Strategy Literature

From the supply chain strategy point of view, we found three articles to be extremely relevant and important to our research. These three papers discussed the issue of supply chains from the strategic perspective to highlight the link between business strategy and design of supply chains.

Porter discusses the issue of strategic alignment in detail by presenting the concept of “activity systems” and different types of “fit” (Porter, 1996). The main idea is to highlight the importance of choosing and coordinating activities in such a manner that every operational action is aligned to the core business strategy. It is a vital for our understanding of the pharmaceutical supply chains by helping us to arranging the pieces of puzzle in a specific manner to identify possible strengths and weaknesses. This argument is sharpened by Fisher in his paper (Fisher, 1997) by highlighting the topic of matching supply chain design with the product demand characteristics. We believe that as a concept, this issue is at the core of current problem faced by the pharmaceutical industry. Fisher advocates that matching supply chain design to the demand characteristics is so vital to the

success of the organization that it should consider developing multiple supply chains, if necessary, to maximize performance.

The problem faced by the pharmaceutical industry is slightly different, however. In addition to the differences in the demand characteristics, there is a very unique problem of incentive alignment between the manufacturer and the distributor. It results in encouraging two very different types of supply chain policies that contradict each other. The prevailing practice in the industry is to operate only one supply to manage everything. In this sense, it will be beneficial for the industry to operate two separate supply chains.

Simchi-Levi (Simchi-Levi and Simchi-Levi, 1999) also discusses a similar idea in their paper, although they highlight additional aspects of the supply chain issues such as the push-pull boundaries. They consider some examples to discuss the practical applications of various options in the context of cost and service levels. In particular, they conceptualize the argument of inventory positioning in the supply chain, based on the ability and quality of the forecast.

## 2.2 Health Care Industry Literature

We will now review some work discussing the general state of the healthcare industry in the United States. Porter and Teisberg, in a collection of articles titled “Curing U.S. Health Care,” evaluate the state of the healthcare system and identify root cause of the problems plaguing the industry (Porter and Tiesberg,

2004). They point out that, “health care costs have outpaced inflation in 13 of the last 17 years, with continued double-digit increases expected.” They attribute this problem to many systemic issues that prevent market forces from operating in this industry.

In particular, Porter and Teisberg shed some light on the problem of cost shifting and the zero-sum game. The absence of a “right kind of competition” in which the focus is on value and not payment is a fundamental problem. They recommend moving to a positive-sum game where the focus is on creating right sets of objectives to drive down healthcare cost. A very detailed view of the pharmaceutical industry supported by industry statistics is provided by Bradley and Weber (Bradley and Weber, 2004). The topic of R&D is studied in detail in the PhRMA report (PhRMA, 2005) as well.

### 2.3 Additional Relevant Literature

Drug distribution plays a very important role in functioning of the pharmaceutical supply chain. It is a hot topic of discussion these days due to the recent developments in the service agreements between manufacturers and distributors. There are multiple reports that describe the traditional and the emerging model in detail (Lehman, 2002) and (Fein, 2003). The blockbuster video model is an interesting concept that is very relevant to the new developments in this space (Cachon and Lariviere, 2003), since the idea of revenue sharing between channel partners has not been explored in the pharmaceutical industry.

The topic of pharmaceutical supply chains is discussed in detail in a few industry reports, for example the Kaiser Family Foundation report (Kaiser, 2005), IBM reports (IBM, 2003), (IBM, 2004a) (IBM, 2004b), and (IBM, 2004c). Of late, pharmaceutical supply chain security has become an important issue and there are many articles that highlight its importance and vulnerability (AHSP, 2002a). Along with security, the problem of shortages is also becoming critically important to the pharmaceutical industry (AHSP, 2002b). The issue of counterfeits is discussed in detail by the FDA (FDA, 2004).

We have reviewed reports prepared by various organizations, such as IBM, Deloitte, Ernst and Young, Datamonitor, and HDMA to supplement our research. Indeed, in addition to the above publications, a lot of articles on the pharmaceutical supply chain are available in various trade journals and company reports that are not discussed here.

## Chapter 3: Industry Profile

### 3.1 Overview

The pharmaceutical industry is unique in many ways. It plays an extremely important role in preserving the health of people, and unlike other goods and services, access to health care services and products is often considered a personal right or universal entitlement. Innovative drugs offer an effective means for the patients to enjoy better health and avoid expensive treatments requiring hospital visits. Studies have shown that each additional dollar spent on newer medicines saves \$4.44 on hospitalizations (PhRMA, 2004) and new medicines generated 40 percent of the two-year gain in life expectancy achieved in 52 countries between 1986 and 2000 (PhRMA, 2004).

Its positive contribution to the society notwithstanding, the pharmaceutical industry remains much maligned. It suffers from a negative image and there is

little awareness of its challenges and problems. Furthermore, pharmaceutical industry's association with the healthcare system – see sidebar, exacerbates the problem and creates real cause for concern for the future of the industry. To make matters worse,

#### Convoluting Health Care System

- Person "A" goes to a local franchise restaurant, and sits down at a table to eat
- Person "B" arrives, looks at the menu, and places an order for "A"
- "B" orders a Diet Coke for "A", but is told the restaurant only offers Diet Pepsi, not Diet Coke
- "B" leaves, and "A" consumes his/her meal
- "A" pays only 15% of the restaurant bill, then leaves
- "C", from Aggregated Eaters, Inc. arrives, picks up the restaurant bill, demands a volume discount, and then pays the restaurant the discounted amount. *This is U.S. health care!*

Source: "What Differentiates Health Care from Other Industries? An Anatomical Overview" by Ernst R. Berndt

the pharmaceutical industry is facing significant new challenges, such as lack of

R&D productivity, parallel trade, and drug counterfeiting, resulting in prices that have outpaced general inflation. As a result, the pharmaceutical industry is struggling to stem the tide of notoriety. But given the number of initiatives afoot to overhaul the convoluted U.S. healthcare system, the pharmaceutical industry can expect some relief in the near future.

Without a doubt, products and services offered by the pharmaceutical industry are of a very different nature than those offered by most other industries. Consequently, the underlying dynamics of the industry are atypical, which in turn bring about strategic and operational differences between the pharmaceutical industry and rest of the market. Although, this research is focused on characterizing pharmaceutical supply chains, a thorough knowledge of forces that make pharmaceutical industry particularly challenging to operate, is essential. To this end, we will take a closer look at various aspects of the pharmaceutical industry that shape its behavior and make it unique.

### 3.2 Key Features

The most distinguishing feature of the pharmaceutical industry is its heavy dependence on the introduction of innovative new drugs to the market. As a result, research and development productivity is the biggest challenge facing the pharmaceutical industry. Therefore, the objective of every other function in this industry is to convert the research and development productivity into sustainable revenue stream.



The marketing and sales along with operations, continuously strive to improve revenues by increasing demand and maintaining very high product availability, albeit at the cost of high inventory levels. A few relationships between key industry characteristics and business strategy are explored in Table 3.1. A comprehensive list of features that make the pharmaceutical industry inherently complex is provided in Appendix 1-Figure 1.

Table 3.1: What Is Different About Pharmaceutical Supply Chain

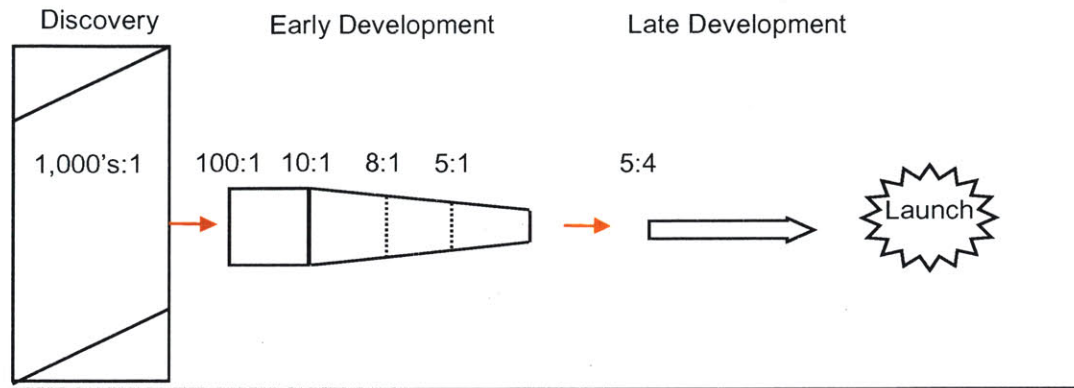
Industry Characteristics	Implications
Low probability of success during product development	Invest large capital at high risk
Until approval, you do not know what you have	Need flexible asset to manage portfolio
Regulation ties market access to process validation	SC design completed years before launch
Registration ties sourcing decision to market access	Limited, slow, and costly sourcing changes
Too many decision makers involved prescribing a drug	Demand for a drug or treatment depends on doctor's preference, health plan, and availability among other things
Cost of inventory vs. value of a sale	Customer service - priority, Inventory control – secondary

Source: Modified from Eli Lilly Company presentation

### 3.3 The Business of Drug Development

Drug development is a very risky business with odds heavily stacked against success. Yet companies bet huge amounts of money on developing new drugs. And so far, the market has richly rewarded such behavior too. Viewed objectively, the Pharmaceutical R&D odds are too long – see Fig 3.1. It can be considered sheer luck if a company is able to launch a new drug successfully. Furthermore, each phase of drug research development, in addition to being

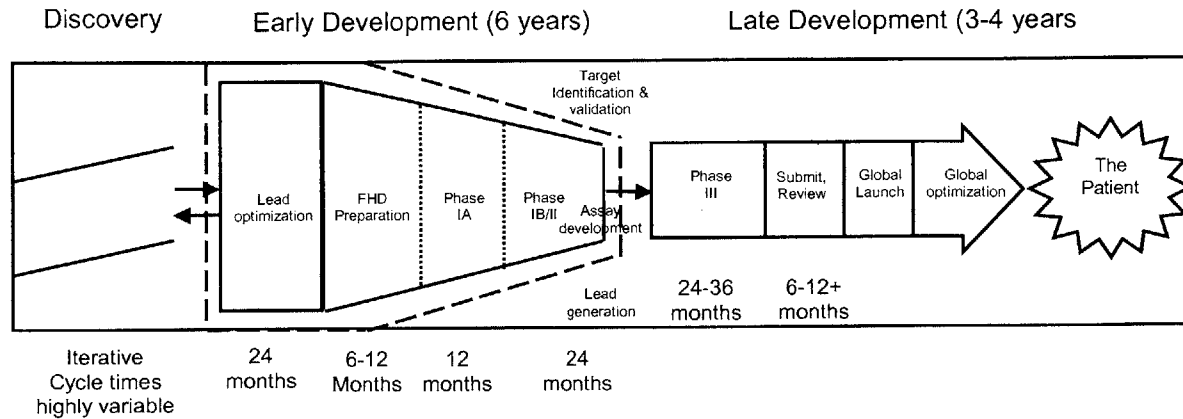
risky and expensive, is very long. The representative durations of various phases is presented in Figure 3.2.



Source: Eli Lilly Company Presentation

Figure 3.1: Odds of Developing a New Drug

There are a number of reasons why companies invest so heavily in this industry. First and foremost is the noble cause of social welfare – a worthy effort that must be applauded. Secondly, the thrill of doing scientific work in itself is a reward for the toiling researchers. Last but not the least is the financial reward to the company if a drug is successful, which more than justifies the risk. The structure depicted in Fig 3.2 is often called the “rocket ship”. It is a graphical representation of the key areas of emphasis in the drug development process. These areas of emphasis correspond to Hypothesis Generation, Candidate Development, and Commercialization.



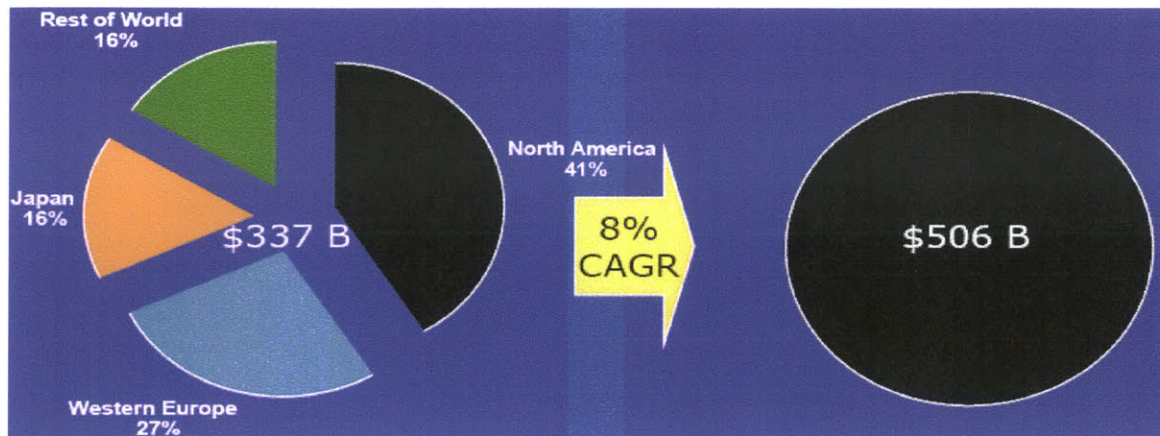
Source: Eli Lilly Company Presentation

Figure 3.2: Drug Development Takes Long Time

Important decisions are made across the value chain as the process progresses from one stage to the next. And the job does not end when a product is launched. Following the product lifecycle management (PLM) approach, appropriate actions are taken at each step to optimize the extraction of value through the entire product life cycle.

### 3.4 A Profitable Business

The pharmaceutical industry has historically enjoyed comfortable profit margins and consequently stable stock prices. The industry has enjoyed annual global growth of 9 to 11% in recent years, a remarkable achievement by any standard (Bradley and Weber, 2004). In fact, during the latest stock market crash pharmaceuticals provided the only silver lining to the otherwise gloomy investment cloud. The pharmaceutical industry in the United States continues to be one of the largest and most profitable industries within the national economy – see Figure 3.3.



Source: IMS Health

Figure 3.3: Worldwide Pharmaceutical Sales

Fortune magazine, in its annual rankings of corporations and industries in the United States discerns the most profitable industries in the country in terms of three measures return on revenues, return on assets, and return on shareholders' equity. Fortune ranks the pharmaceutical industry at or near the top in all three of these measures, as follows:

- ☞ Return on revenues - 14.3% profits as percent of revenues in 2003, ranking third overall, in a measure in which the median was 4.6% for all of the five hundred corporations ranked in the study.
- ☞ Return on assets - 10.3% profits as percent of assets in 2003, ranking second overall, in a measure in which the median was 3.1% for all of the five hundred corporations ranked in the study.
- ☞ Return on shareholders' equity - 22.1% profits as percent of shareholders' equity in 2003, ranking fourth overall, in a measure in which the median was 12.6% for all of the five hundred corporations ranked in the study.

Source: Fortune

The shine, however, seems to be coming off the once high flying industry. There are increasing concerns about the continued financial success of the pharmaceutical business model due to a number of recent internal as well as external developments. The dramatic rise in the cost of R&D, the pricing pressure from managed care organizations and government agencies – see

#### Pharmacoeconomics

Already European countries have introduced punitive health reforms to curb expenditure on pharmaceuticals and protect their socialised healthcare systems. In 1999, for example, the UK established the National Institute of Clinical Excellence (NICE), to act as an advisor to government on whether or not new medicines, technologies, and treatments should be made available on the National Health Service. In March 2002, NICE restricted access to three pharmaceuticals for treating colorectal cancer.

Source: From, "World healthcare: The end of the boom", 1 June 2003, Economist Intelligence Unit - Executive Briefing

sidebar, the increasing presence of generics, and the loss of patent protection on key products are starting to have an impact on industry's financial performance.

Furthermore, recent changes in the government regulations, such as the Sarbanes-Oxley Act of 2002 and FDA's current Good Manufacturing Practices (cGMP) for the 21st century have exacerbated the situation by exerting more pressure on a flagging industry. In other words, the problems are slowly but steadily growing in number and gathering momentum, suggesting an impending proverbial "perfect storm." The industry is at a stage where significant strategic shifts in the corporate policies are the only effective means to stage a recovery.

The solutions available to the industry to remedy the situation fall into two separate categories namely, improve R&D productivity or improve operational

efficiency - two diametrically opposite opportunities in terms of risks and rewards. Judging by the response of the leading companies, it appears that the industry is responding aggressively by manipulating levers traditionally at its disposal to improve R&D productivity. Some of the actions initiated by the industry are:

- ☞ increase expenditure on sales and marketing efforts
- ☞ increase expenditure on R&D efforts to sustain the rate at which profitable new products arrive onto market
- ☞ consolidate (M&A) to benefit from bigger operations to gain productivity improvements in R&D and sales activities

The response of the pharmaceutical industry is not at all surprising given its heavy investment in R&D and Sales and Marketing - see Table 3.2. The strategy to invest heavily in R&D and marketing is driven by what is popularly known as the “blockbuster model.” Following this strategy, large pharmaceutical companies hinge their fortunes on development of a blockbuster drug – loosely defined as a drug with sales exceeding \$1 billion a year.

Table 3.2: Allocation of Funds

	<u>%</u>
Revenues	100.0
Cost of goods sold	25.3
Selling and general administration	32.8
Research and development	14.0
Taxes	7.3
After-tax net profit	20.6

Source: Health Affairs, Jan/Feb 2004

In comparison, COGS is a mere 25%. As a result, gains to the bottom line resulting from operational efficiency improvements are not considered comparable to that arising from the discovery of a blockbuster drug. But an often overlooked fact is that manufacturing and distribution typically account for about

40 percent of the headcount and 60 percent of the capital employed in a large pharmaceutical firm. So, these are obvious areas in which to look for savings and short-term productivity improvements, especially in a time of declining growth. An effective manufacturing and distribution capability can help a company extract the maximum value out of every product.

### 3.5 Supply Chain Structure

A unique feature of the pharmaceutical industry is that it operates two very different types of supply chains at all times. One supply chain supports the drug development phase and the other one to sell a successful drug in the market. Obviously, the objectives and constraints active in these two phases are very different requiring very different types of supply chain capabilities. While one supply chain is focused on facilitating a quick completion of the clinical trials to obtain a quick approval, the aim of the other supply chain is to meet sales targets.

As a result the drivers motivating the supply chain design are speed and high availability respectively. Important considerations in both cases include safe custody and special handling requirements. A simple inspection will, however, reveal that, in general, the pharmaceutical industry lays little emphasis on its supply chain operational efficiency.

### 3.5.1 The Trial Supply Chain

The complexities in this phase arise due to the difficulty in forecasting the needs of a trial medicine at numerous small sites. Furthermore, it is very difficult to know in advance if a site will be a heavy or a light patient enroller. Since the trial medicines are developed in small batches, matching demand and supply is important to ensure availability according to patient needs, which change at a short notice. Given the laser like focus of the trial on drug approval, supply chain responsiveness is critical; buffering uncertainty with inventory is not a viable option due to shelf life limitations and cost concerns. Thus, the key to success in this phase is agility and readiness to respond to any contingency.

### 3.5.2 The Pharmaceutical Supply Chain

After a drug is launched, a completely different set of objectives, drivers, and constraints become dominant. Now, the focus shifts from agility to high availability. Consequently, there is a dramatic shift in the models and techniques employed to support this phase of drug life cycle. A typical pharmaceutical supply chain after a drug launch is depicted in Figure 3.4.

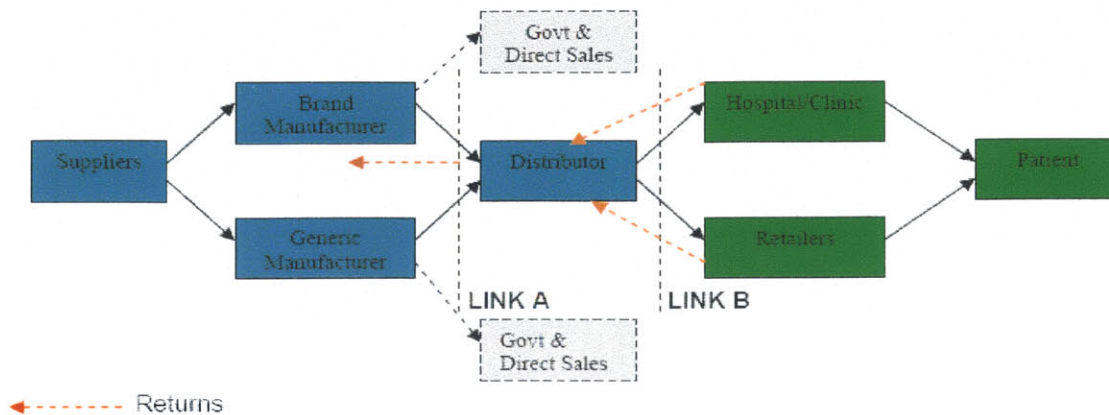


Figure 3.4: The Pharmaceutical Supply Chain



In this phase, the complexity of the pharmaceutical supply chain results from the involvement of multiple large independent organizations of very diverse nature. The key stakeholders in this supply chain include multiple government agencies, hospitals, clinics, drug manufacturers, drug distributors, pharmacy chains, retailers, research organizations, and the FDA. To compound matters further, the same supply chain is responsible for the distribution of prescription drugs, over-the-counter (OTC) medicines, generics, as well as biologics having different handling needs and operational objectives.

Indeed, there are numerous other organizations, such as insurance companies, healthcare management organizations, and GPOs (not included in Figure 3.4), that further increase the complexity. Due to very different business objectives, these organizations make the task of managing supply chain all the more difficult. Furthermore, due to the regulatory nature of the industry and numerous merger and acquisitions to acquire more R&D expertise, many pharmaceutical supply networks have grown in an uncontrolled fashion rather than being planned for optimal performance.

### 3.5.3 Latest Trends and Drivers

It is important to identify the prevalent trends and fundamental drivers to obtain a better understanding of the pharmaceutical supply chain structure. These forces broker the underlying dynamics that define the relationships between various supply chain constituents. In Table 3.3, we present a set of key trends and

drivers along with our assessment of their scope, the likelihood of the trend to continue in the future, its degree of relevance, and the intensity of impact on the supply chain.

Table 3.3: Latest Trends and Drivers

Trend/Driver	Scope	Odds	Rel	Impact	Comments
Increasing average cost to develop a new drug, from discovery to approval.	S	4	4	4	More pressure to push sales and hence more inventory in the pipeline—see Appendix 1-Figure 2.
R&D productivity is on the decline.	S	4	3	4	Drug approvals doubled over the past three decades, but annual R&D spending increased more than 12 times. Likelihood of fewer blockbuster will put pressure on operations—see Appendix 1-Figure 3.
Prescription drug spending increases have outpaced other expense categories.	S	4	4	5	Lead to more pressure to lower prices, which will direct focus to operations—see Appendix 1-Figure 4.
Over-The-Counter medicines will grow as patents expire.	S	5	5	5	OTC/Generics require a very different type of supply. Fewer branded drugs will further erode the margin buffer and put pressure on operations – see Appendix 1- Figure 5.
Direct sales to customers (pharmacies, hospitals, etc.) decreased from 27% (1999) to 20% (2001). This is expected to reach 17% by 2005 (Gautrin, 2002).	O	3	5	5	Consolidation being pursued favoring indirect distribution. Direct model, however, can't be ruled out and may gain strength.

Increasingly leaning towards an indirect distribution mode (wholesalers and chain distribution centers) only 13% of orders are shipped directly to chain stores (Gautrin, 2002).	S	3	5	5	Indirect distributor is gaining strength but pricing issues are threatening its destruction. Lot of confusion in this area.
More outsourcing of logistics functions along with management, design, printing and distribution of literature to specialized companies.	T	4	5	4	This decision will allow organizations to salvage major storage areas for finished products.
Use postponement strategies by becoming flexible to manufacture a product centrally, but move the packaging fulfillment and distribution closer to the customer, instead of building production sites around a specific product.	S	5	5	5	A paradigm shift for this industry to start focusing on operational efficiency by borrowing ideas from other industries and supply chain principles.
Slowly moving to demand-driven replenishment.	S	3	5	5	Learning from leading CPG companies.
Operationally efficient manufacturers jockeying to capture market share.	S	3	5	5	Manufacturing process is key to drug approval, hence critical for IP.
Industry consolidation due to M&A activities - see Appendix 1-Figure 6.	S	3	5	5	Trend may reverse due to unproductive R&D.

Type: S/T/O/NA – Importance level, S-Strategic, T-Tactical, O-Operational, NA-Not Applicable  
Odds: Scale (0 to 5) – Likely to continue. 0-No, 5-Imminent  
Rel: Scale (0 to 5) – Relevance to supply chain performance. 0-Negligible, 5-Maximum  
Impact: Scale (0 to 5) – Severity of consequences. 0-Negligible, 5-Maximum

### 3.5.4 Industry Issues

The pharmaceutical industry is riddled with fundamental problems which inhibits its rapid transformation. As a result of its peculiar environment, these problems have a debilitating effect on every aspect of the industry, especially the supply chain operations. A quick assessment of some recent issues that have plagued operational efficiency is presented in Table 3.4.

Table 3.4: Industry Issues

Issue	Scope	Rel	Impact	Comments
Many product failures during development are ultimately attributable to problems relating to the transition from laboratory prototype to industrial product.	T	2	4	Better management will lower the overall cost due to better R&D productivity. Also, it allows for more predictable commercialization.
Lack of interest in new technology due to concerns about regulatory impact.	T	3	4	Leads to low utilization, product wastage, high inventories & compliance problems driving up costs & lower productivity.
The FDA is encouraging generics competition with benefits, such as -abbreviated New Drug Application -180 day marketing exclusivity for first-to-file generics players.	S	2	5	Revenue from generics sales is expected to exceed \$50B mark within the next 3 years. More players imply a faster loss of market and hence the need for better end-of-life management.
Manufacturers treated QC symptoms, not causes—making significant tactical investments in after-the-fact quality management measures.	O	4	4	Led to more quality issues, increasing variability and lead times. Such issues result in a vicious cycle of low productivity and higher cost.
Excessive rework and scrap -industry average for both rework and discarded product is 50%.	O	4	4	As mentioned above, interrelated issues lead to the spiral of productivity loss and

-A single scrapped batch can represent between \$3M and \$4M to the enterprise <sup>1</sup> .				hence higher cost.
High work-in-process (on-hold) and finished goods inventory levels—				Same as above.
Many manufacturers report on-hold inventories at the 40 to 60 day level (100 days not unheard of) <sup>1</sup> .	O	4	4	
Long & unpredictable cycle times				
-Manufacturing cycle times fall in the 30 to 90 day range. A batch release can take up to 60 days.				Same as above. Due to long lead times, the planning horizons start creeping up resulting in more problems creating a negative feedback loop.
-Cycle times typically double in nonconformance scenarios because of the time needed to detect, trace, resolve, correct, and document process deviations.	O	4	4	
-Up to 6 days to detect a nonconformance and conduct an investigation <sup>1</sup> .				
Low capacity utilization—plant utilization is around 50% <sup>1</sup> .	S/T	5	5	Capacity is very expensive to add and takes a long time to build. Due to regulatory issues, outsourcing also takes time.
Significant laboratory non-value-add bottleneck activities contribute 90% to the cycle time. The laboratory can add as much as 75% to this cycle time <sup>1</sup> .	T	3	5	Symptomatic of significant underlying problems that can lead to bigger problems than simply wastage of capacity and quality issues.
Threat of counterfeits is increasing globally (FDA, 2004).	T	4	5	Requires better security of supply chain, adding to cost and delays. Brand protection is a huge concern, not to mention social cost.
Retail and pharmaceutical markets must absorb more than \$2 billion/	T	4	3	Approximately 1,300 recalls in 2001 alone. This adds cost to

year in product returns caused by overstocked or outdated products <sup>2</sup> .				the supply chain due to logistics, wasted capacity, and destruction. Safety and environment are big concerns.
Fewer new products in the pipeline.	S	0	5	Threatens the future of the company resulting in quick fixes, such as M&A.
Increasing price pressure from the large health management organizations.	S	3	5	Exposes the operational inefficiency in the system by squeezing the margin. May lead to myopic decision jeopardizing the future.
Globalization of drug manufacturing.	S/T/O	5	5	Along with competition it makes the supply chain more prone to quality and safety problems.
Increase in parallel trade.	T	3	4	Demand becomes more unpredictable. Also undermines the business model of the company by challenging the pricing strategy. Safety also becomes a concern.
Informed customers and the spread of internet.	T	3	4	Demand management is possible through DTC and ecommerce channels. Also improves sales reps productivity.
Recalls of blockbuster drugs, such as VIOXX.	S	0	5	Undermines the image of the FDA and company resulting in increased scrutiny causing product pipe line congestion. The trials will become longer, larger, and costly. Not to mention the cost of lost sales, damaged goods, logistics, and destruction for the company.

The R&D and sales and marketing functions of major pharmaceutical companies are suffering from declining productivity.

S 0 5

Specialized biotech firms are threatening to outperform the large pharmaceutical companies, whose strategic response is M&A.

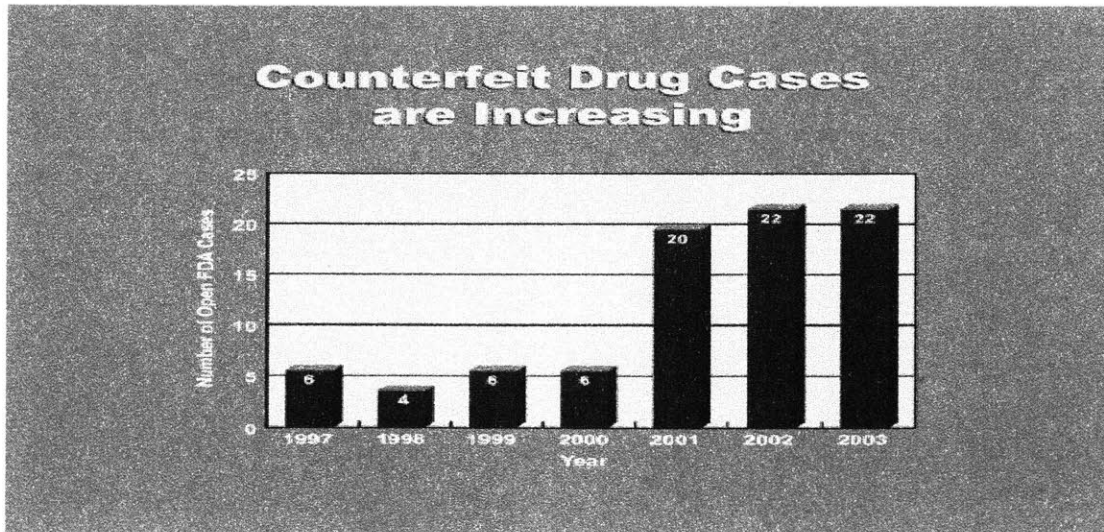
Too many M&A to boost pipeline.

S 4 5

Results in destruction of value on many fronts. The industry hasn't seen any R&D productivity gains due to M&A and in addition we have broken supply chains decreasing operational efficiency.

Type: S/T/O/NA – Importance level, S-Strategic, T-Tactical, O-Operational, NA-Not Applicable  
 Rel: Scale (0 to 5) – Relevance to supply chain performance. 0-Negligible, 5-Maximum  
 Impact: Scale (0 to 5) – Severity of consequences. 0-Negligible, 5-Maximum  
 1. Source: Pharmaceutical Quality: Build it into the process. AMR Research Report, May 2004  
 2. Source: Hintlian, J., and Proud, S., "RFID: The Pharmaceutical Supply Chain's Newest Remedy," ASCET

Two issues that are fast becoming very worrisome are counterfeiting and drug shortages. The FDA is extremely worried about the growing problem of counterfeits – see Figure 3.5, and released a detailed report on how to curb it.



Source: Combating Counterfeit Drugs: A Report of the Food and Drug Administration, February 2004.  
 Figure 3.5: FDA Open Investigations from 1997-2003

In a recent report, the Pharmaceutical Security Institute indicates that counterfeiting, theft, and diversion of prescription drugs rose by 16% worldwide in 2004. Additionally, according to the USA Today report, the United States reported the highest number of incidents for the second year in a row. Of the 553 incidents reported worldwide last year (up from 477 in 2003,) 76 took place in the United States, while 60 occurred in Columbia, and 59 were in China. For counterfeit events alone, the United States ranked fifth.

Similarly, the problem of drug shortages is also on the rise. This is a surprising trend given the razor sharp focus of the industry on fill rates; a stated objective of the pharmaceutical industry is to maintain very high service levels. But despite industry's best effort, results are not very good (it is important to recall here that the current inventory levels in supply chain are at an all time high.) Some recent statistics highlighting this problem are noted below:

- ☞ 40 drugs or vaccines are currently unavailable or in short supply (The Wall Street Journal, 2/15/02).
- ☞ according to Linda Tyler- University of Utah drug-information center, "Five or six years ago, there were 8–10 shortages a year. Last year there were about 30. This year, we've had 40 new shortages." (*The Wall Street Journal*, 2/15/02).
- ☞ according to George Hartpence of the New Jersey Hospital Association, it was uncommon to see more than one or two drugs on backorder in the 80s and 90s, now it is not uncommon to see as many as four dozen drug items on backorder (*AP*, 12/8/02).



While pharmaceutical manufacturers play a crucial role in ensuring adequate supply, wholesalers, pharmacies, and hospitals play an equally critical role in ensuring that patients are served effectively. The main reasons for shortages include (Tyler and Mark, 2002),

- ☞ regulatory issues (7%)
- ☞ product discontinuation (20%)
- ☞ raw materials issues (8%)
- ☞ manufacturing problems (28%)
- ☞ supply and demand problems (10%)
- ☞ approximately 27% of shortages are unexplained

In general, there are four categories of problems that can cause shortages (Johnston, 2004).

☞ Manufacturing Problems

- slowdowns/shutdowns
- cGMP
- raw materials difficulties
- ramp-up during approval requiring small lot size and short shelf life

☞ Economics

- Going out of business
- Economic incentive to produce (balancing liability and profitability)

☞ Demand forecasting

- Forward buying
- Just-in-time inventory
- Regional shortages
- Additional uses/unforeseen market growth

☞ Unique Risk

- Potential for mortal or serious injury
- Potential for injury to unintended recipients

The problems arising due to poor forecasts are central to the efficient operation of any supply chain. In general, product shortages occur when unexpected demand for a product exceeds production capability (the premise here is that organizations are able to match supply with demand successfully, as long as the demand is predictable and there is enough time to make corrections.)

In the pharmaceutical industry, poor forecast accuracy may result from:

- ☞ New indication for an existing product
- ☞ Unusual disease outbreak
- ☞ New product sales dramatically exceeding expectations
- ☞ Inaccurate demand forecasting techniques
- ☞ Just-in-time (JIT) inventory levels unable to meet demand spikes
- ☞ Off label usage by prescriber
- ☞ Domino effect from shortage of a related product
- ☞ Hoarding that exaggerates a potential shortage
- ☞ Contract awards that produce large demand shifts in a short period of time

### 3.6 Inventory Management

A recent U.S. Census Data reports that pharmaceutical inventories in the U.S. have doubled in the past decade and are approaching nearly \$18 billion. In the meantime, the industry also had a realization that throwing more inventories at the supply chain does not always guarantee that product availability targets are met. But, due to the highly segmented nature of the market, inventory management in the pharmaceutical industry is inherently difficult.

The complexity of inventory management problem results from multiple inventory policies, volume variability, seasonality, and local attributes or events. It is further compounded by the pressure to respond quickly. The key issues related to inventory management are listed in Table 3.5.

Table 3.5: Inventory Management Issues

Issue	Comments
Recent economic pressure to cut cost tied up in inventory.	The total inventory in the supply chain is at all time high around \$18 billion.
Meet very high service levels.	A key requirement with ethical and financial implications prompting over cautious approach for extreme over-buffering on inventory levels leading to unnecessary economic waste.
Inventory positioning.	Classic problem of why, where, when, & how much inventory.
Inherent uncertainties in Supply and Demand.	Due to numerous product/market combinations, regulatory restrictions, and safety concerns present a tough challenge.
Lack of data integrity.	Makes it extremely hard for planners to forecast and decide with confidence how much inventory of each item should be kept at any point in the chain at any time.
Large global supply chains characterized by numerous product supply chains having different markets.	Although the impact of globalization is limited compared to other industries due to its regulatory nature and safety concerns, still it adds complexity to address local regulations and localization requirements.
Lack of visibility into the overall inventory picture.	The pharmaceutical supply chain is a layered structure where different layers act mostly in isolation. Efforts are afoot to change this going forward.

### 3.7 Reverse Logistics

Managing product returns in the pharmaceutical industry is much more than a simple logistics challenge. Due to the sensitive nature of drugs and their potential health and financial implications, management of returned goods is a

serious business with legal ramifications. Let us now take a closer look at the two main reasons of product return, namely drug recall and drug expiration.

*Drug Recall:* Drugs can be recalled either due to a temporary problem with the product or a permanent removal of the drug from the market due to drug safety related issues. In either case, drug recall is a major event that creates numerous problems, not the least of which is the tarnished reputation of the company. From operations standpoint too it poses a significant challenge in terms of orchestrating the removal of every unsold item from every point in the supply chain. As a result, there are sudden shifts in the volume of recalled drug in the network leading to capacity issues - a shortage resulting from a temporary recall or an excess due to a permanent recall - requiring immediate attention.

*Drug expiration:* It is normal to expect a small percentage of drugs to remain unsold for a long time and eventually expire. An occurrence that is exacerbated by the industry wide practice of carrying high levels of finished goods inventory. In general, the expired drugs are removed from the customer locations and destroyed by licensed companies. In many cases, the manufacturer will accept the expired drug and refund a certain percentage of the price back to the buyer too. It is extremely important for the drug manufacturers to carefully monitor the quantity and pattern of drug expiration. An analysis of this data can be used to evaluate and tune existing inventory policies and forecasts.

Each drug return incidence has following implications:

- ☞ logistics difficulties (coordination of product removal)
- ☞ financial implications (lost sales, cost of removal, cost of drugs removed)
- ☞ environmental hazard resulting from disposal of chemicals
- ☞ special handling of narcotics
- ☞ legal ramifications
- ☞ accounts reconciliation

### 3.8 Customer Segments

The United States pharmaceutical market can be segmented into the following major customer groups:

- ☞ chain pharmacy - a store that fills prescriptions and a group at least 4 stores
- ☞ independent pharmacy - a store that fills prescriptions 1-3 store chain
- ☞ mail order - a facility that fills prescriptions by mail, which includes Internet pharmacies and pharmaceutical benefit managers
- ☞ hospitals - including accounts at the address of the hospital
- ☞ food stores with pharmacy
- ☞ clinics, that is, a physician or group of physicians located at the same address
- ☞ mass merchandisers with pharmacy, includes any mass merchandiser or discount store with a pharmacy
- ☞ nursing home and long term care facility not located at a hospital

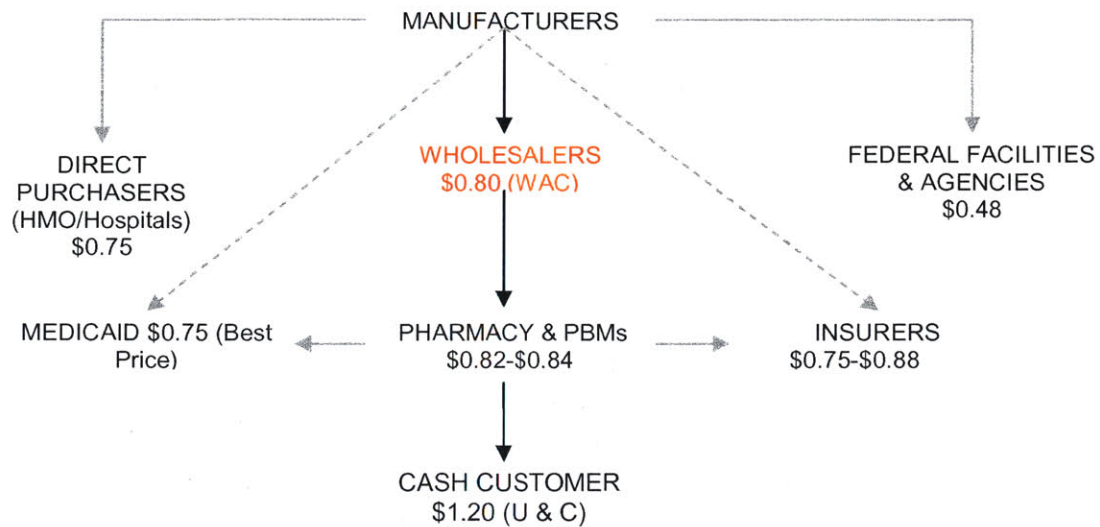
Source: Bear Stearns, February 2002

Each one of the segment listed above have a unique demand profile and ordering pattern. As a result, catering to such a diverse group of customers, and maintaining very high service levels, exerts tremendous pressure on the supply chains. Indeed, the safest response of the industry in such a situation is to maintain high inventory levels.

### 3.9 Complex Pricing Mechanism

The pharmaceutical industry is notorious for instituting a convoluted pricing mechanism. A simplified version of the pricing structure is shown in Fig 3.6.

Prices indicate the amount paid for a drug with Average Wholesale Price of \$1.00 per tablet



Source: Adapted from The Profit in Pills: A Primer on Prescription Drug Prices with permission of the Alliance for Retired Americans, 2001

Figure 3.6: Pricing Chains

### Channel of Distribution Levels and Price Terminology for Pharmaceuticals

The levels of the "channel of distribution" for pharmaceuticals include manufacturers, wholesalers, retailers and consumers.\* Buying and selling occurs at each level in the channel of distribution, with specific terms applied to costs or prices at each level. In some cases, different terms used at different levels can refer to the same dollar amount.

Manufacturers: *Their selling price* (to wholesalers, primarily) = Average Manufacturer Price (AMP). (Manufacturers also set the Wholesale Acquisition Cost (WAC) as a suggested list price for sale to wholesalers.) Best Price (BP) is the manufacturer's lowest selling price to wholesalers.

Wholesalers: *Their cost to buy drugs* (from manufacturers) = Wholesale Acquisition Cost (WAC). (A manufacturer's selling price (AMP) may = the Assigned Wholesale Acquisition Cost (WAC), but the AMP may be lower.)

*Their selling price* (to pharmacies) is determined using either a "cost plus" or a "list less" approach. The resulting price might be very similar using either approach:

"Cost Plus" = Wholesale Acquisition Cost (WAC) plus a markup percent.

"List Less" = Average Wholesale Price (AWP) less a discount percent.

Retailers (Pharmacies) : *Their cost to buy drugs* (from wholesalers) = Actual Acquisition Cost (AAC). Sometimes pharmacies buy drugs directly from manufacturers; in that case, AAC = AMP. The Medicaid program uses Estimated Acquisition Cost (EAC) as their best estimate of AAC. *Their selling price* (to consumers):

To Uninsured and Indemnity-Insured Consumers = The "Usual & Customary" (U & C) retail price which includes the cost of the drug plus the pharmacy's markup.

To Other Insured Consumers ("Service Benefit" Insurance Coverage) = The insurer's payment formula, typically including its determination of the cost of the drug dispensed ("ingredient cost") plus what it allows for a professional dispensing fee. The pharmacy submits a claim to the insurer equal to the formula-based price less the consumer's cost-sharing amount (the copayment or coinsurance).

Consumer: *Their cost to buy drugs* (from pharmacies):

If uninsured = U & C price. (Customers with indemnity insurance will pay U & C price and are reimbursed that amount less any cost sharing.)

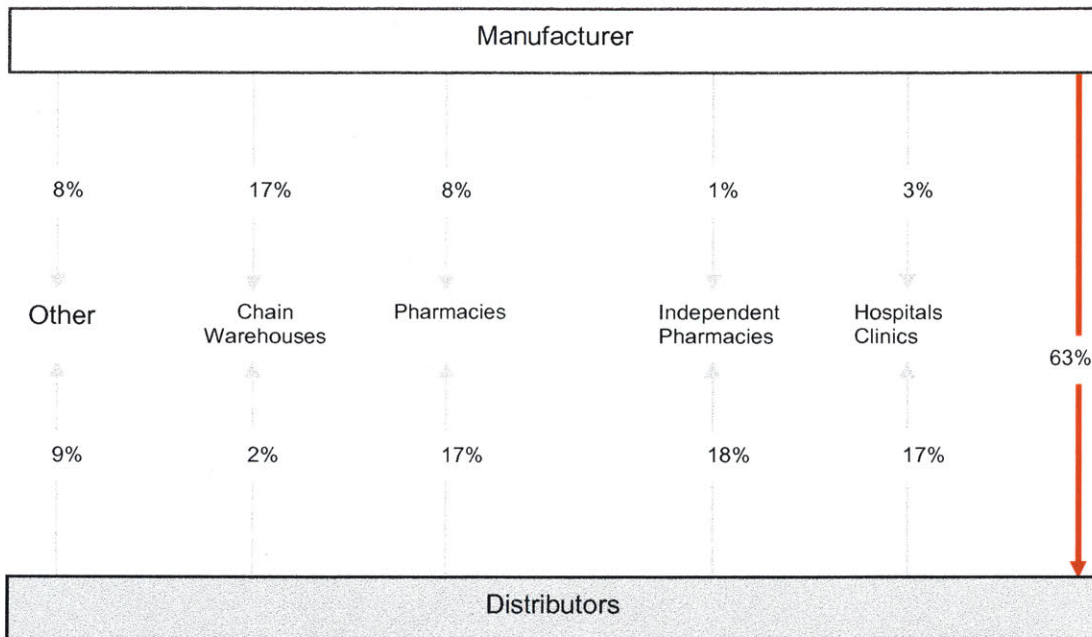
If insured = Copayment or coinsurance amount.

In the current environment, it is almost impossible to figure out the actual cost of a drug due to the presence of multiple pricing contracts between several parties that are involved in the process of drug procurement. Furthermore, due to the prevalence of discounts and special contractual arrangements between different stakeholders, a significant amount of time and money are spent on reconciling the accounts between these parties.

### 3.10 The Wholesale Distributor

The wholesale distributors play a vital role in the day-to-day functioning of the pharmaceutical supply chain – see Figure 3.7 for volumes handled by distributors.

In addition to facilitating the movement of products between manufacturers and customers in a reliable, safe, and efficient manner, the distributors also provide numerous services, such as extension of credit and receivables management.



Source: Adapted from "The Role of Distributors in the U.S. Healthcare Industry," a study conducted by Booz Allen Hamilton as commissioned by HDMA, 2004.

Figure 3.7: Proportions of Branded Prescriptions Volume (2002) – Total \$173B

Indeed, demands placed on the distributors are very stringent. Specifically, the distribution system must efficiently serve more than 130,000 pharmacy outlets in the United States every day on demand. Pharmacy customers expect fill rates in excess of 99% (adjusted for back orders), and a typical pharmacy relies on the distributor to have more than 10,000 SKUs accessible for delivery, often within 12 hours (HDMA, 2004).

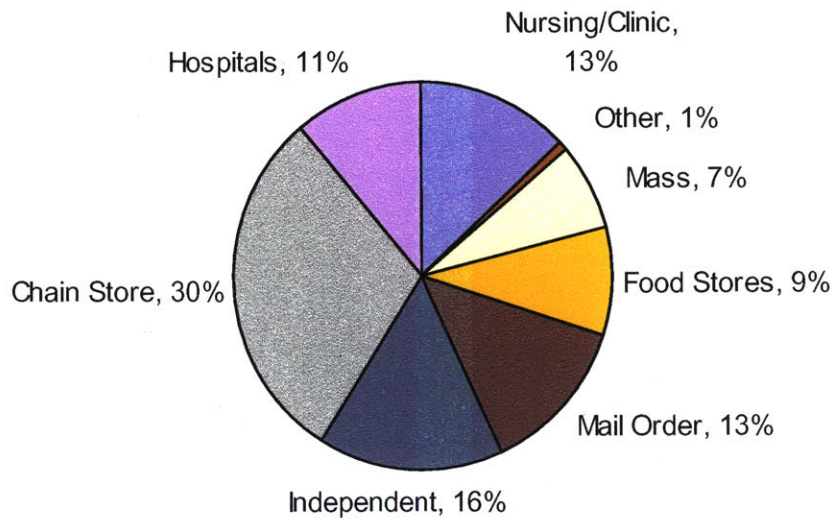


The distributors' share of industry volume has been very stable over the past decade, averaging 63 percent, reflecting their historical role as an efficient and valued partner to the pharmaceutical industry (HDMA, 2004). The study carried out by HDMA went on to conclude that the distributors add significant value by lowering the overall cost of fulfillment. The scale of their operation allows distributors to deploy latest technologies and achieve economies of scope and scale resulting from consolidation of various demand and supply signals.

It is easy to argue that distributors operate in a very environment, given the peculiar nature of the healthcare industry. Every component of the industry is subject to regulations and requires a high level of safety precautions. The products, the information, even the prices are under one kind of control or another. Any negligence can be costly. The peculiarities of the industry inevitably lead to more complexity, which in turn adds more layers of processes to the overall system rendering it inefficient. Some prominent features of the environment that have a direct impact on the distributors are (HDMA, 2004):

- ☞ Strict government regulations
- ☞ Large number of proprietary manufacturers
- ☞ Proliferation of SKUs
- ☞ Large and diverse customer base
- ☞ Extremely fast ramp up and ramp down of demand
- ☞ Very short turnaround time
- ☞ Special handling requirements
- ☞ Safety is key to prevent counterfeits
- ☞ Perishable product
- ☞ Multiple very diverse product lines

As mentioned previously, the pharmaceutical industry supports a number of customer segments with unique needs. As a result, offering customized service is very critical for maintaining competitiveness in this industry, consequently, a rise in operational complexity is a forgone conclusion. The break up of the customer and sales volume is shown in Figure 3.8.



Source: Adapted from "The Role of Distributors in the U.S. Healthcare Industry," a study conducted by Booz Allen Hamilton as commissioned by HDMA, 2004.

Figure 3.8: Customer Segmentation Based on 2002 Dollar Sales Volume

So far, the distributors have responded very effectively by maintaining very high service levels despite the constrained operating environment. Thus, it appears that given the special nature of the industry and the necessity to maintain high service levels, deep involvement of the distributors in the pharmaceutical supply chain is essential. An overview of distributor's role in facilitating a smooth operation of the pharmaceutical supply chain is presented in Table 3.6.

Table 3.6: Wholesale Distributor Value Proposition

Process	Value Proposition
Manufacturing	Inventory information to facilitate manufacturers' production planning and scheduling.
Order Processing	<ul style="list-style-type: none"> <li>• Reduced number of transactions required by aggregating orders</li> </ul>
Pharmacy Management	<ul style="list-style-type: none"> <li>• Automated order processing systems to reduce overhead requirements</li> </ul>
Fulfillment Logistics	<ul style="list-style-type: none"> <li>• Warehousing of broad assortment (20K+ SKUs across branded, generic, OTC, and health and beauty supplies).</li> <li>• Next-day or same day delivery</li> <li>• Aggregation of shipments into customer stores/ware house</li> <li>• Repackaging and relabeling</li> <li>• Special handling (e.g., controlled substances, biologics, vaccines, frozen, and blood products)</li> <li>• Rapid distribution of new products at launch</li> <li>• Emergency logistics to reallocate scarce inventory during crises</li> </ul>
Financial Management	<ul style="list-style-type: none"> <li>• Chargebacks for contract pricing differentials</li> <li>• Aggregation of pharmacy receivables risk for manufacturers</li> <li>• Simplified working capital management for retailers via JIT shipments</li> </ul>
Sales and Marketing	Marketing programs (e.g., co-op, promotions, identify programs)
Pharmacy Management	<ul style="list-style-type: none"> <li>• Inventory management solutions</li> <li>• Pharmacy systems</li> <li>• Generic sourcing</li> <li>• Private labels</li> </ul>

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Source: Adapted from "The Role of Distributors in the U.S. Healthcare Industry," a study conducted by Booz Allen Hamilton as commissioned by HDMA, 2004.

## **Chapter 4: Case Study I – Eli Lilly and Company**

### **4.1 Company Background**

Eli Lilly and Company (Lilly) was founded on May 10, 1876. Lilly is best known for its widely popular antidepressants Prozac and Serafem, but the company develops medicines for a wide variety of ailments. Lilly belongs to a select group of pharmaceutical companies that invest heavily in research and development to bring innovative drugs to the market for areas with unmet market needs, such as cancer, diabetes, pain, cardiovascular disorders, psychological problems, and respiratory problems.

But unlike many of its competitors, Lilly's product portfolio consists mainly of patented drugs, commonly known as Branded drugs. Lilly's top selling drugs include pancreatic cancer treatment Gemzar, osteoporosis medication Evista, Humalog insulin, diabetes drug Actos, and erectile dysfunction treatment Cialis (developed with ICOS). In addition to neurological, oncological, and diabetes drugs, the company also makes antibiotics, growth hormones, anti-ulcer agents, and cardiovascular therapies, as well as animal health products.

### **4.2 Fundamentals**

Lilly has an illustrious history that goes back more than 128 years. The company is headquartered in Indianapolis, Indiana, USA. Lilly employs more than 44,000 employees worldwide, of which, approximately 8,400 employees are engaged in research and development in facilities located in 9 countries. It conducts clinical

research in more than 60 countries. Lilly products are sold in 143 countries; it owns manufacturing plants in 13 countries. Lilly has been voted as one of the 100 Best Companies to Work for in America for six consecutive years by *Fortune* magazine and one of the Best Companies for Working Mothers (in the top 10 for the fifth time in 9 years) by Working Mother magazine (company website).

#### Key Financials-2004[23]

(dollars in millions)

Net sales	\$13,857.9
Net income-as reported	\$1,810.1
Capital expenditures	\$1,898.1

#### Research and Development -2004

Total expenditures	\$2,691.10 /year \$224.30 /month \$51.80 /week \$10.40 /workday
Increase from previous year	\$340.90
R&D as a percentage of sales	19%
Total R&D investment in last five years from continuing operations	\$11,444.20
Employees engaged in Lilly R&D	8450
Percent of total work force	19%

Source: Company Website

No other pharmaceutical company had a more successful 2004 than Lilly, as the company launched an unprecedented seven products in the past two year.

Crediting a very productive staff, which has more physicians than many other R&D staffs in the world, executives believe that the rest of the decade will be as fruitful.

This outpouring is very much against the trend of the times as majority of the drug manufacturers have been experiencing a decrease in R&D productivity. Lilly's industry-leading product launches are the result of several actions taken in the last decade to improve productivity and create leading-edge capabilities in research and development. These include a financial commitment that is at the top of the industry relative to sales – see Table 4.1. In addition, the company has recruited top talent from academia as well as from industry to enhance its capabilities.

Table 4.1: R&D Investment by top Pharmaceutical Companies

Company Name	R&D expenditure in 2004	% Higher than in 2003	% of sales in 2004
Pfizer	\$7.68 billion	3%	15%
GlaxoSmithKline	\$5.20 billion	8%	14%
Sanofi-Aventis	\$5.19 billion	8%	16%
Novartis	\$4.21 billion	12%	15%
Roche	\$4.10 billion	7%	16%
AstraZeneca	\$3.80 billion	10%	18%
<b>Eli Lilly and Co.</b>	<b>\$2.69 billion</b>	<b>15%</b>	<b>19%</b>

Source: Med Ad News, 24 (3): 1, March 2005.

Table 4.2 compares Lilly's performance with the market and its main competitors. It is clear from the comparison that Lilly holds a strong competitive position in a very challenging industry and has a bright future.

Table 4.2: Competitive Landscape

Key Numbers	Eli Lilly	GSK	Novo	Pfizer
Annual Sales (\$ mil.)	12,582.5	38,238.0	4,501.0	45,188.0
Employees	46,100	100,919	18,800	122,000
Market Cap (\$ mil.)	67,890.8	125,854.9	19,426.6	231,053.7

					Industry- Market
<b>Profitability</b>					
<b>Gross Profit Margin</b>	82.26%	83.33%	78.54%	89.95%	82.83% 49.53%
Pre-Tax Profit Margin	24.62%	28.90%	27.20%	19.45%	23.85% 9.13%
<b>Net Profit Margin</b>	18.61%	20.47%	17.96%	15.62%	17.67% 5.88%
Return on Equity	24.0%	81.2%	19.3%	12.1%	22.9% 12.2%
<b>Return on Assets</b>	11.1%	20.5%	14.2%	6.7%	10.9% 2.1%
Return on Invested Capital	18.0%	42.8%	18.7%	10.9%	18.4% 5.9%
<b>Operations</b>					
Days of Sales Outstanding	64.69	114.31	59.35	65.39	68.72 54.95
<b>Inventory Turnover</b>	1.3	1.7	1.0	0.8	1.6 8.1
<b>Days Cost of Goods Sold in Inventory</b>	282	206	354	439	224 44
<b>Asset Turnover</b>	0.6	1.0	0.9	0.4	0.6 0.4
<b>Financial</b>					
Current Ratio	1.31	1.66	2.45	1.46	1.61 1.50
Quick Ratio	0.9	1.4	1.1	1.1	1.1 1.1
Leverage Ratio	2.17	3.96	1.36	1.80	2.11 5.89
Total Debt/Equity	0.49	1.10	0.07	0.29	0.38 1.35
Interest Coverage	79.60	24.80	42.70	(81.60)	30.20 2.70

Source: Hoovers Inc. report builder

### 4.3 Supply Chain Infrastructure

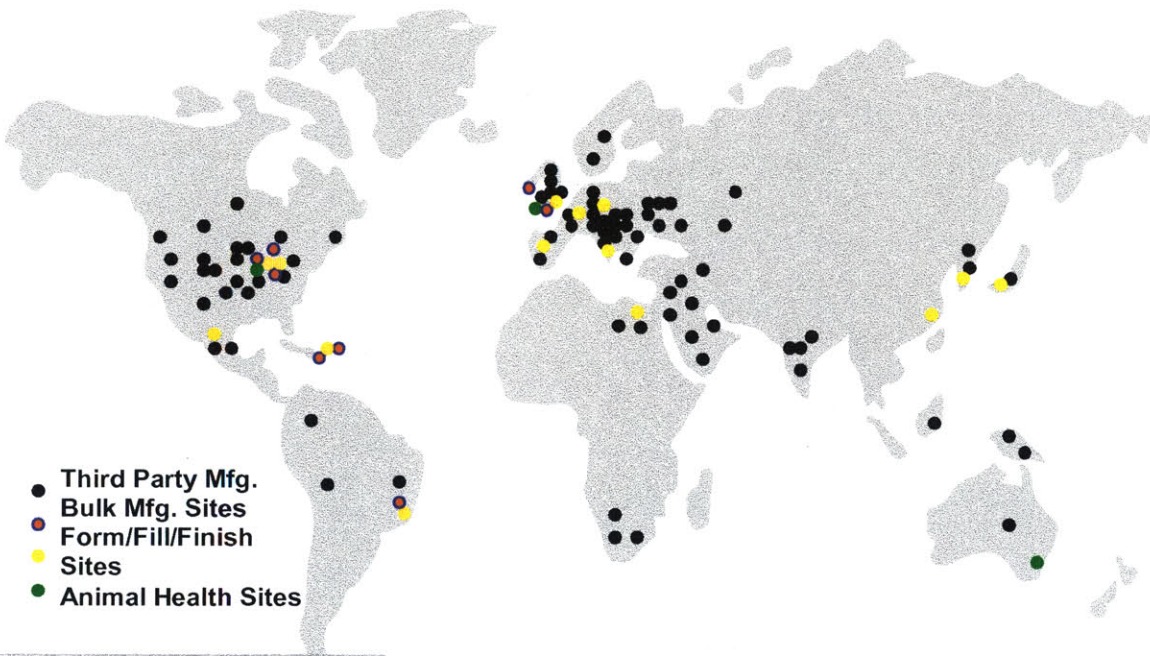
During the past few years, in addition to investing in research and development programs Lilly has invested heavily in rationalizing its infrastructure through capacity addition, upgrade, and reconfiguration. As a result, the number of manufacturing sites has grown significantly, which is also a reflection on the increasing strength of Lilly's growth portfolio. A break up of the manufacturing infrastructure by locations is given below – also see Figure 4.1.

Base load manufacturing sites:

Indianapolis, IN;	Lafayette, IN;	Clinton, IN;	Ireland;
Carolina PR;	Mayaguez, PR;	Spain;	France;
Germany;	Italy;	England	

Regional manufacturing sites are located in:

Brazil; Mexico; China; Egypt; Japan; Multiple third parties



Source: Eli Lilly Company Presentation

Figure 4.1: Manufacturing - Current Global Locations

Lilly Owned Mfg.

25 Plants  
 21 Sites  
 16 Countries  
 \$3 B Asset Base

Third Party Mfg.

> 80 TPOs  
 33 Countries

Product Scope

60 Products  
 8,000 SKUs  
 Sold in 161 countries  
 \$1.7B Inventory  
 \$1.9B Expense  
 18.7% COPS  
12000 Mfg. Employees

Source: Eli Lilly Company Presentation

Figure 4.2: Manufacturing Infrastructure



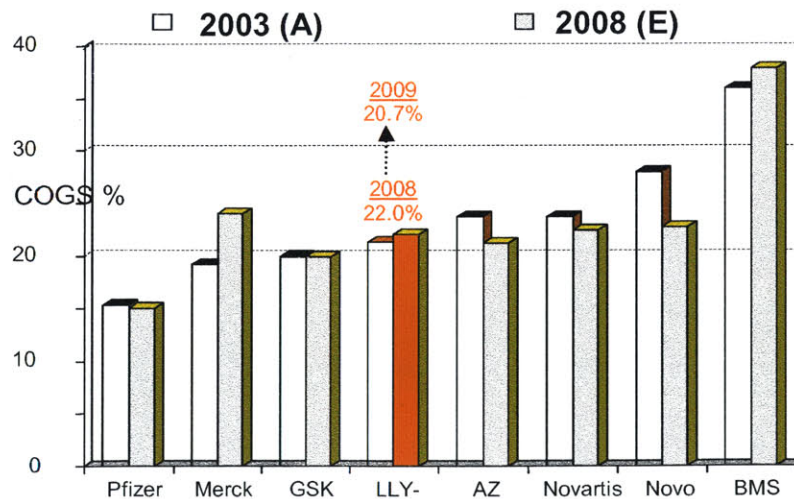
Major new facilities under consideration:

- Puerto Rico - biotechnology facility for Humalog
- Indianapolis - freeze dryers
- Prince William, VA - parenteral facility for insulin
- Italy - parenteral facility for insulin

Major new third party manufacturer's being brought on line:

- Greece - Freeze dried capacity for non- U.S. Gemzar
- Italy - Freeze dried capacity for non- U.S. products
- U.S. - Contingency capacity for insulin
- U.S. - Freeze dried capacity for Xigris, and others

It is important to note that a key measure of Lilly's operational performance, i.e., cost of goods sold (COGS), is higher than its competitor and projected to remain on the higher side - see Figure 4.3, primarily due to the nature of its product portfolio and the strategy to focus heavily on in-house manufacturing. The impact of the higher cost on profit, however, is more than compensated by financial and ethical reasons demanding superior product quality and high service levels.



Source: Wall-Street Analyst reports-First Call 2004

Figure 4.3: Wall-Street projected %COGS

### 4.3 Manufacturing Process

Indeed, drug discovery and approval are the most difficult phase of any drug creation process, but manufacturing a drug too has its own set of challenges that require careful planning and execution. In this section, we will discuss some important aspects of the drug manufacturing process (note that for the purpose of this report, we are focusing only on small molecule drugs.)

The key steps involved in the production of a drug are listed below (Figure 4.4):

- ☞ Make Active Product Ingredient (API) - a multi-step large scale manufacturing process
- ☞ Store API
- ☞ Ship API
- ☞ Make Formulation and Finish - bulk tablet, nude vial – semi finished product
- ☞ Store (and perhaps ship) semi-finished product
- ☞ Package finished product
- ☞ Store Finished product
- ☞ Ship to first paying customer.

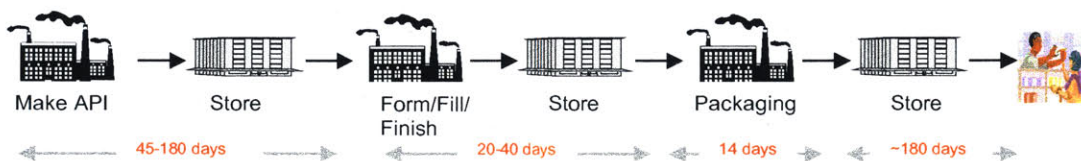


Figure 4.4: Lilly's Manufacturing Process

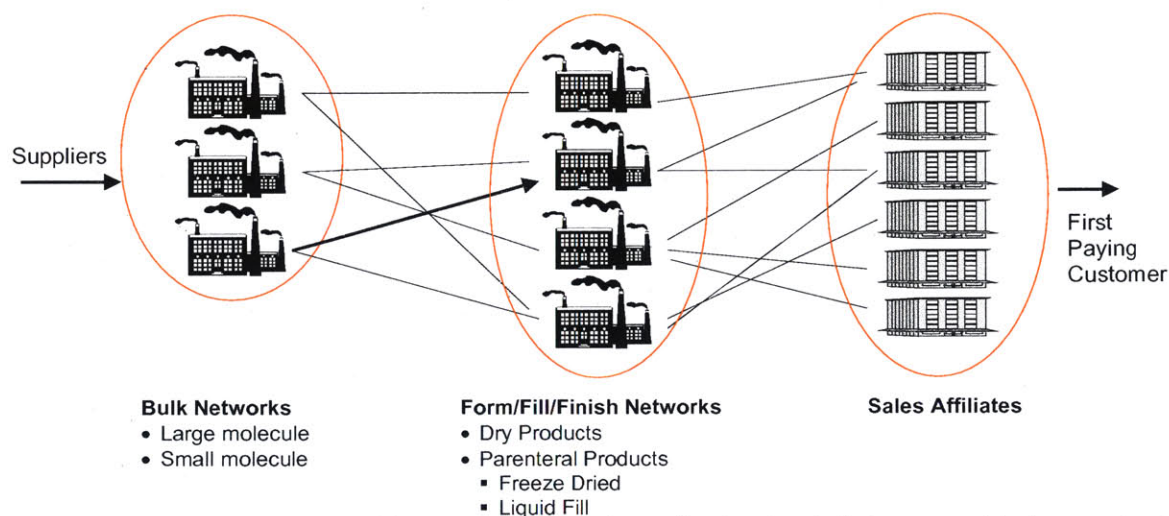
Typically, producing an API takes 45 days of active processing time in a dedicated facility; since many of the facilities manufacture multiple products compounded by the multi-step nature of each process, the manufacturing cycle times can be as much as 180 days. The Form/Fill/Finish is a quicker process, typically running from 20-40 days followed by final testing of the finished product

which takes 2 weeks. In case of quality issues or deviations, additional time must be spent to resolve problems by performing a detailed root-cause analysis.

Although the number of such problems can be predicted fairly accurately, the time to resolve problems varies significantly since it is driven by the severity of the deviation, which is hard to predict. In total, the "active processing time" for the supply chain is around 100 to 250 days. This number includes the transfer time from process step to process step and from site to site, along with the "hold" time related to campaign strategies. The total lead time exceeds one year if the storage in strategic inventory is also included, of which, the value added tasks account only for a small fraction (approximately 10%) of the total time spent in the supply chain. It should be noted that warehousing raw material and finished drugs is also a complex process that requires approval from the FDA. Due to the sensitivity of the chemicals to humidity, temperature, and limited shelf life, warehousing is effectively an extension of the manufacturing process.

In addition, to obtain an approval for a drug's efficacy and safety from FDA, the manufacturer must obtain an approval for the process and site where the drug will be manufactured. Approval of a site by FDA is called registration and it is a multi-year process. The manufacturing processes have to follow the guidelines issued by FDA known as Current Good Manufacturing Practices (cGMP.) As a result, the flexibility of switching products and sites at a short notice is not an option for a drug manufacturer.

One approach to protect against vagaries of nature and market in face of this crippling constraint is to simultaneously register multiple sites for multiple products that share similar manufacturing process. In Lilly, such groups of plants with common technology are called ‘Manufacturing Networks’ – see Figure 4.5. An inevitable consequence of such a strategy is the increased complexity of the manufacturing infrastructure due to an increase in the number of products, manufacturing technology, and number of registered sites.



Network: a group of plants with common technology allowing loads to be moved between plants.

Source: Eli Lilly Company Presentation

Figure 4.5: Manufacturing Networks

It is clear from Table 4.3 that current trends are pointing towards an increasingly complex environment at Lilly, which in turn has huge implications for the smooth operation of its supply chain. At the same time, increasing complexity also suggests that supply chain management is becoming more important in meeting manufacturing objectives and consequently a key determinant of corporate success – a hallmark of an excellent supply chain.

Table 4.3: Increasing Complexity

	1990s	2003	2007
# of key products	4	6	15
Legacy Products	120+	89	10-15
Utilization	Moderate	High	Moderate
FDA Expectations	Moderate	High	Higher
Japan	Very limited	Complex	More complex
Tech Transfer	Few	Many	More
Technology	Small molecule & BHI & KPB	Small molecule & BHI & KPB & MCC & S-V E.coli & pens	Small molecule & BHI & KPB & MCC & S-V E.coli & pens & other alternative delivery

Source: Eli Lilly Company Presentation

#### 4.4 The Shifting Focus

Today, the impact of systems thinking is visible in every industry. Not to be left behind, the pharmaceutical companies too have been undergoing a series of transformations in the past two decades to move away from the traditional silo mentality. Companies are realizing that tremendous opportunities exist to make significant improvements if they think beyond improving a single function to include all functions in the value chain. Taking cue from other industries, pharmaceutical companies have also started treating manufacturing as an integral part of firm's business model, despite the fact that the COGS is relatively very small.

Research And  
Development

Manufacturing

Sales and  
Marketing

As shown in Figure 4.6, Lilly also expanded its scope, resulting in the expansion of its manufacturing network.

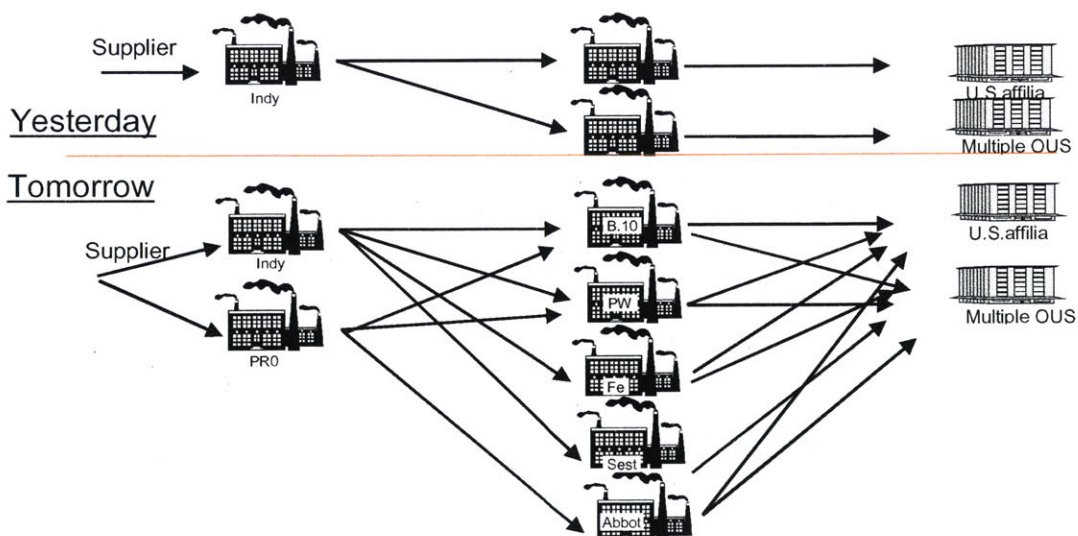
<u>1982 - Local focus</u>	<u>1992 - Regional focus</u>	<u>2002 - Global focus</u>
Manufacturing plants report to local affiliates	Plants have regional reporting structure	Plants have global reporting structure by network
Mainly local production	Regional production	Global production-many nodes
Presence sites in Europe as well as Intercontinental	Some presence benefits in Europe as well as intercontinental	Reducing presence benefits in Europe less tied to specific products
Local launches of non-global products	Few global product launches	Many global product launches with global processes
Optimize local site to meet affiliate need	Optimize regional capacity	Optimize global network capacity
Cost focus	Cost focus	Revenue generation focus

Driven by:  
 Decreased trade barriers  
 Increased regulatory standards and manufacturing costs, pricing pressures, speed to market

Source: Eli Lilly Company Presentation

Figure 4.6: Shifting Focus

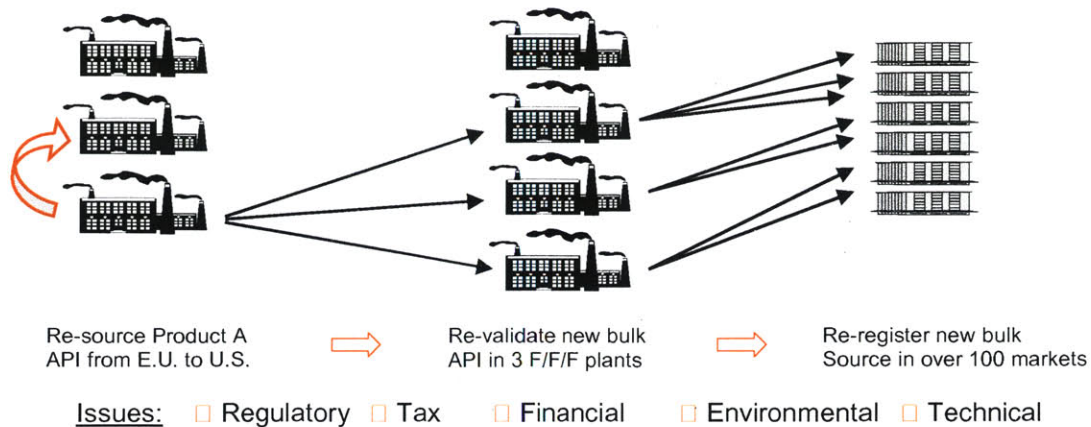
Indeed, this shift has posed a serious problem to the supply chain design and operation. As illustrated in Figures 4.7 and 4.8, the complexity of the supply chain increased dramatically due to a slight change in the network requirements.



Evista is moving from 2 DPN sites and 1 bulk to 4 DPN and 3 bulk sites  
 Gemzar is moving from 2 parenteral sites and 1 bulk site to 4 parenteral sites and 1 bulk site.

Source: Eli Lilly Company Presentation

Figure 4.7: Humalog Example of Added Complexity



Source: Eli Lilly Company Presentation

Figure 4.8: Cascading Effect of a Change on the Manufacturing Network

Consequently, designing and operating the supply chain at Lilly is a tremendous challenge due to the brittle nature of its supply chain and the pressure to deliver very high customer service levels.

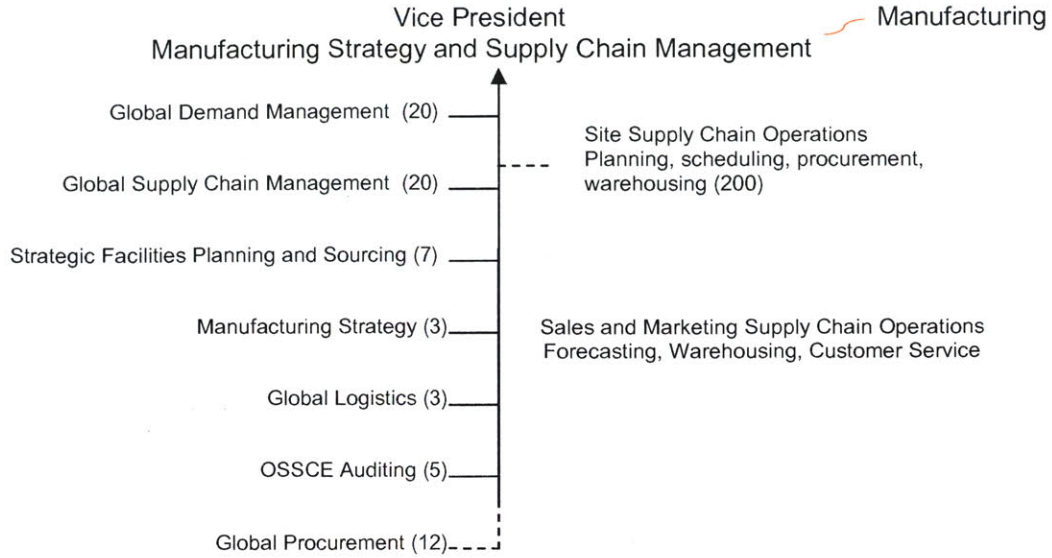
#### 4.5 Supply Chain Organization

The supply chain function falls under the purview of the manufacturing division.

The detailed organization structure supporting the supply chain practice at Lilly is given in Figure 4.9. Key Manufacturing Strategy and Supply Chain

Organizational areas are as follows:

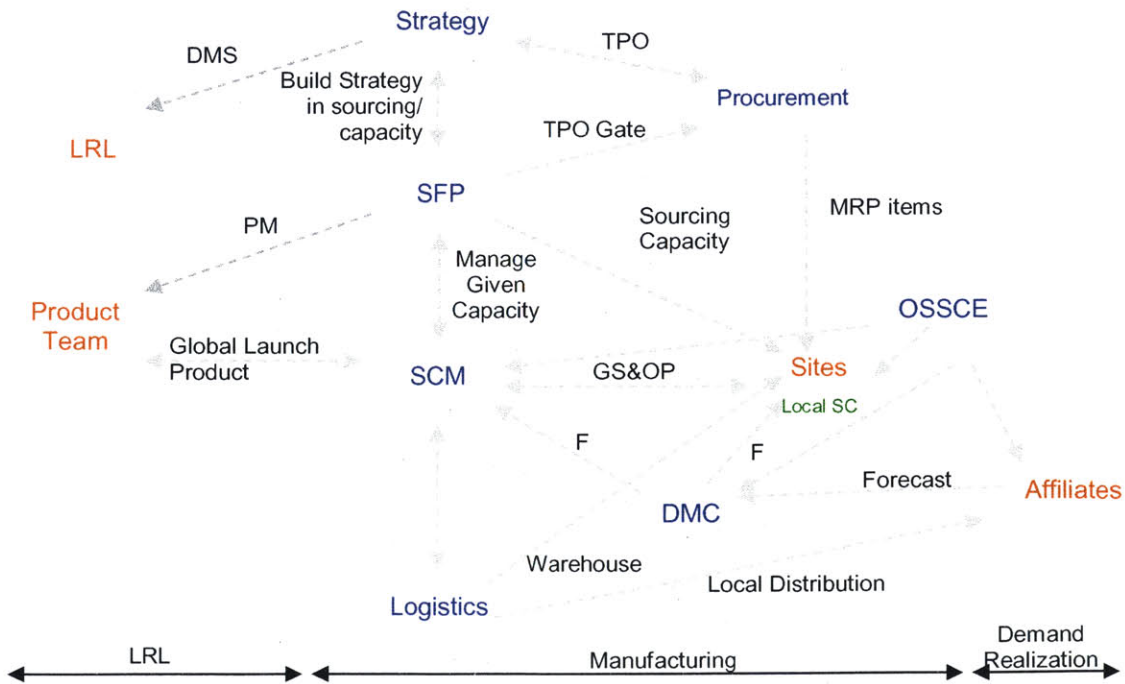
- ☞ Strategy
- ☞ Strategic Facilities Planning and Sourcing (SFP)
- ☞ Supply Chain Management (SCM)
- ☞ Demand Management Center (DMC)
- ☞ Global Logistics
- ☞ Global Procurement
- ☞ Operational Standards for Supply Chain Excellence auditing (OSSCE)



Source: Eli Lilly Company Presentation

Figure 4.9: Supply Chain Organization Structure

The linkages between various groups and associated function are shown in Figure 4.10. In particular, the linkages highlight processes, tasks, or actions that connect various nodes.



Source: Eli Lilly Company Presentation

Figure 4.10: Corporate MSSC Linkages



Raw material quality and availability have a huge impact on the ability of a pharmaceutical company to manufacture drugs for the market. The pharmaceutical companies, however, are uniquely limited in their ability to control these factors. In most cases, there are only a handful of suppliers of critical raw materials and manufacturers are the mercy of their capability to maintain supply. An act of nature or a regulatory concern at a single plant can cripple the supply of the raw material to the whole world for a long duration.

The pharmaceutical companies respond to this situation by maintaining large stocks of such raw materials at all times. Since the cost of raw material is negligible compared to the opportunity cost of a lost sales, it is advisable for the pharmaceutical companies to retain this policy. Additionally, as described earlier, the pharmaceutical supply chain have long lead times, thus, in the event of a raw material supply problem, the company can realign its resources to take advantage of the time buffer and make necessary adjustments.

As a result of this peculiar situation, the role of raw material procurement is rather straightforward as compared to other industries. The supplier base is typically very small and purchasing decisions are simple. Lilly also follows the policy of holding large stocks of key raw material and has never missed a sale due to unavailability of raw material.

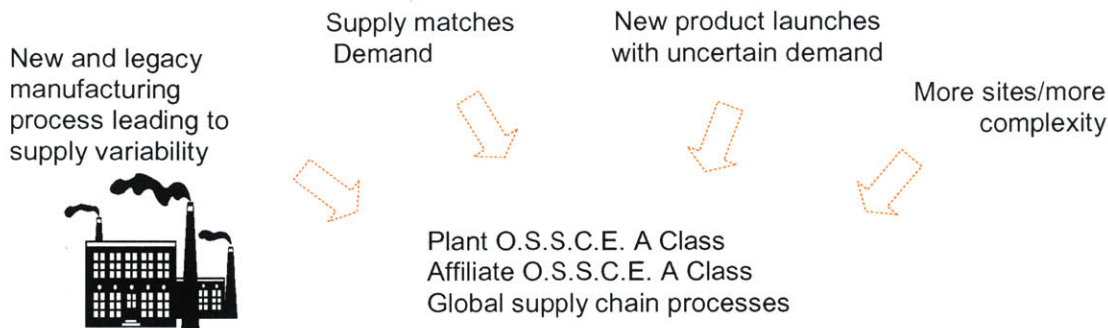
## 4.7 Long Term Strategy

It is a strong belief in Lilly that tight integration of supply chain function with R&D and Sales & Marketing is critical to the success of the company. An integrated process approach is used to increase business opportunities, increase speed to market, and reduce cost. A detailed description of Lilly's view on integration is given in Appendix 2-Figure 1; Figures 2 and 3 in Appendix 2 highlight the key aspects of Lilly's journey towards a highly integrated firm and a virtual firm.

In order to move towards a highly integrated company, it is essential that Lilly institutes good, consistent supply chain processes that are critical in managing the increasing complexity and uncertainty. And, a concrete step in this direction is the O.S.S.C.E. class A certification process. Obtaining O.S.S.C.E. Class A certification for Supply Chains requires,

- ☞ changing who makes decisions
- ☞ operating as a network and supply chain, not just individual sites & affiliates
- ☞ aligning network resources to implement decisions
- ☞ approving and implementing one plan globally

It is believed that O.S.S.C.E will help Lilly achieve success in terms of better customer service at a reduced working capital. An O.S.S.C.E based integration approach is presented in Figure 4.11.



Site supply chain role is to

- Optimize site capacity
- Customer service and communication to affiliates. Proactive communication on order status
- Link with affiliates and build relationship

Central Supply chain's role is to

- Help networks optimize capacity across the network
- Look across the supply chain to optimize inventory throughout the supply chain
- Link with product teams (communicate, understand the business, allocation) for long term supply & strategic issues
- Develop, improve, train and audit supply chain processes

Source: Eli Lilly Company Presentation

Figure 4.11: Lilly's Journey towards Integration

In conclusion, the supply chain management effort implies many things, such as:

- ☞ it's about revenue maximization and risk reduction
- ☞ design and operate supply chains to enhance customer service
- ☞ focus on risk management and mitigation
- ☞ design and operate reliable and robust supply chains
- ☞ partner with development to deliver:
  - Robust process control strategy
  - Flexible process and technology platform
  - Competitive yield
- ☞ partner with Sales & Marketing to deliver:
  - Good short-term forecast (local country management owns S&OP)
  - Good long-term forecast
- ☞ in an increasingly complex environment, collaborate
  - Manufacturing functional collaboration – Process Engineering, Science & Technology, Quality
  - Corporate functional collaboration – Sales & Marketing, R&D
  - Business partner collaboration – R&D, Sales & Manufacturing TPO

## 4.8 Key Performance Indicators

The supply chain organization tracks multiple performance indicators to make sure that the supply chain is functioning properly and goals will be met as planned. There are two tiers of indicators that are monitored routinely. At a higher level, the first order indicators, such as customer service levels, capacity utilization, inventory, and operational efficiency at an aggregate level are used by senior management to measure performance. This is supported by a detailed measure of indicators for each individual supply chain separately. Different organizations monitor different KPIs as shown below:

### ☞ Customer Service:

- Actual percentage of lines shipped complete and on-time
- Actual adjusted on-time delivery compared to the customer service level target established by the Sales/Market Affiliate

### ☞ Demand Management

- 12-month forecast average for all SKU's
- Forecast completeness for all products
- New product introduction forecast completeness
- Dependent demand forecast completeness
- Dependent demand forecast accuracy

### ☞ Supplier Performance

- Supplier delivery performance
- Orders placed with full lead times
- Purchase order stability
- Late purchase order and stock order transfers

### ☞ Third Party manufacturing

- Dependent demand requirement completeness
- Dependent demand accuracy
- Inventory accuracy of the consignment at third party manufacturer

#### ☞ Inventory Management

- Monthly comparison of actual DOS with target DOS inventory level
- Monthly comparison of actual with target minimum and maximum inventory levels
- Monthly tracking of slow moving inventory
- Accumulated actual inventory losses
- Actual cycle count of finished good inventory

#### ☞ Others

- New product launch readiness (a combination of inventory level and registration status)
- Special issues (narrative)

### 4.9 The Future

Information technology (IT) holds the key to success of all future improvement effort. A robust IT infrastructure is a must to enable solutions that can handle increasingly complex scenarios. To this end, Lilly is developing an IT infrastructure that is built on a foundation of:

- ☞ Standardized equipment within a network
- ☞ Standardized manufacturing processes and controls
- ☞ One global formulation for a product.

It is being developed to meet the new needs to improve the current supply chain flexibility – see Fig 4.12.

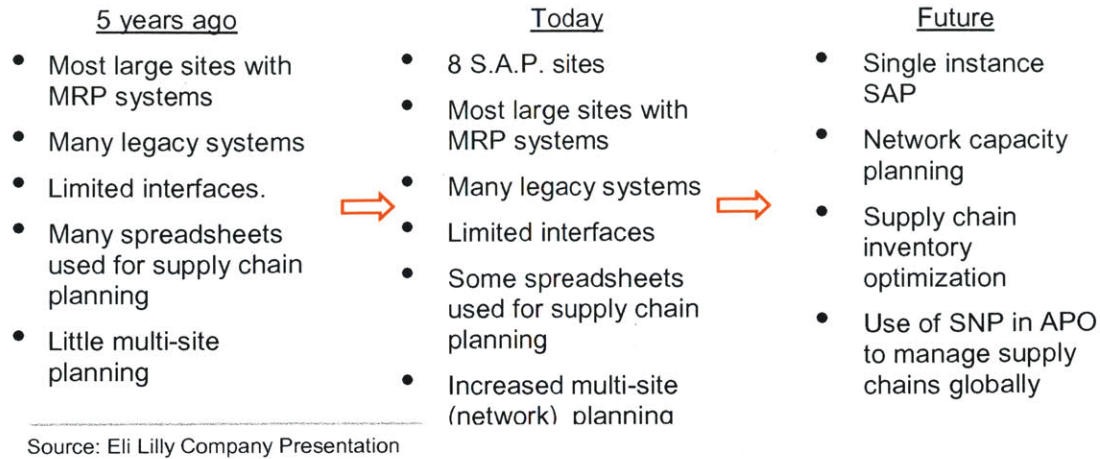


Figure 4.12: Future State of IT Systems

To further increase the effectiveness of the existing infrastructure and the future initiatives, following projects will be launched:

- ☞ continue global SAP implementation
- ☞ assess whether sites S&OP should be built on Global S&OP
- ☞ culture change
- ☞ skill training and qualification in standard processes

## **Chapter 5: Case Study II - Cardinal Health Inc.**

### 5.1 Company Background

Cardinal Health (Cardinal) started as Cardinal Foods, a food wholesaler, in 1971 in Ohio. In 1980, Cardinal switched businesses to focus solely on pharmaceuticals distribution. It went public in 1983 as Cardinal Distribution and grew by acquiring other distributors initially, but later acquired companies in related fields as well.

In all, since 1980, Cardinal has acquired more than 40 companies. As a result, Cardinal is a collection of a number of organizations that till recently functioned semi-autonomously under the overarching control of the holding company. It is only now that efforts are afoot to streamline the management of different groups and bring everything under the umbrella of the Cardinal Health logo.

Cardinal is the second largest distributor of pharmaceuticals and other medical supplies and equipment in the US behind McKesson. Broadly speaking, the company has four business segments – see Figure 5.1, namely,

- ☞ pharmaceutical distribution and provider services
- ☞ medical products and services
- ☞ pharmaceutical technologies and services
- ☞ automation and information services

The pharmaceutical distribution business is the largest business segment and includes such services as hospital pharmacy management, consulting, and staffing.



**Pharmaceutical Distribution & Provider Services**

- Drug distribution & logistics
- Blood products
- Radio-pharmaceuticals
- Formulary consulting
- Pharmacy management
- Franchised retail stores



**Medical-Surgical Products & Services**

- Manufacturing
- Distribution
- Provider consulting
- Medicine safety consulting



**Pharmaceutical Technologies & Services**

- Drug development services
- Drug delivery systems
- Manufacturing and packaging
- Product launch acceleration
- Product life cycle extension



**Automation & Information Services**

- Automated dispensing
- Clinical and market information

Source: Company Website

Figure 5.1: Four Main Business Segments

## 5.2 Fundamentals

The stated corporate vision of Cardinal is to “Build a diverse portfolio of market leading businesses integrated around healthcare providers and pharmaceutical manufacturers.”(Cardinal, 2005) Cardinal maintains 100% focus on health care and aligns all its products and services to broaden its lead in this area. Cardinal is constantly extending its reach, both upstream and downstream to offer a variety of services. It is involved in diverse activities, such as manufacturing drugs and packing materials, packaging drugs, distribution of medical and surgical products, lab products, drugs, materials management services, and hardware/software to provide patient bedside care.



Cardinal plays an important role in facilitating the pharmaceutical supply chain operations in the U.S., as evident by the following facts (company website):

- ☞ manufactures pharmaceuticals for 9 out of the top 10 pharmaceutical companies and most leading biotech firms
- ☞ develops, manufactures, and packages more than 500 million doses of pharmaceuticals (6,000 per second)
- ☞ manufactures more than four million medical/surgical products, including surgical instruments, respiratory products, suction tubing, gowns and gloves, in 31 facilities worldwide
- ☞ makes over 40,000 deliveries of pharmaceutical and medical/surgical products
- ☞ picks and delivers more than two million pharmaceutical products for 35,000 customers nationwide
- ☞ delivers unit-doses of radiopharmaceuticals to 90 percent of U.S. hospitals within 3 hours
- ☞ handles one out of every six pharmaceutical products dispensed to U.S. patients

To support its products and services, Cardinal owns 31 medical/surgical manufacturing plants and 47 medical/surgical distribution centers, along with 24 pharmaceutical distribution centers in the U.S. It also owns 38 pharmaceutical manufacturing, laboratory, and packaging facilities in 11 countries. Its customers include hospitals, independent pharmacies, and retail chains. It also offers management services and handles inventory, logistics, and other administrative tasks for customers.

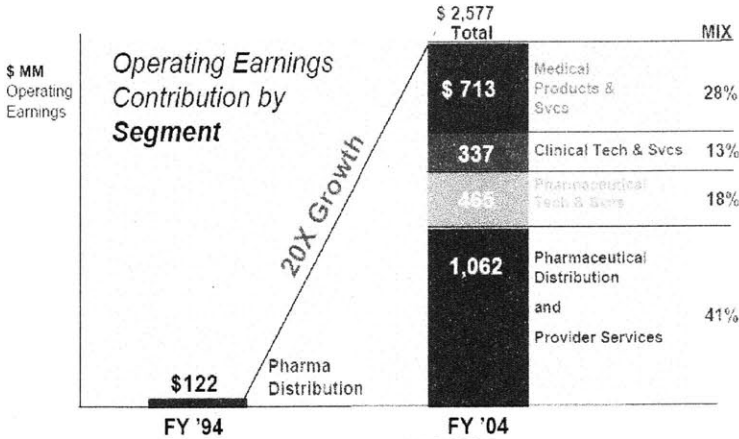
Although Cardinal is composed of four main business segments, the pharmaceutical distribution segment is the dominant segment – see Table 5.1.

Table 5.1: Contributions from Various Segments – 2004 Sales

Business Segment	\$ mil.	% of total
Pharmaceutical distribution & provider services	54,231.0	84
Medical products & services	7,357.6	11
Pharmaceutical technologies & services	2,804.1	4
Automation & information services	680.8	1
Other	(20.0)	-
<b>Total</b>	<b>65,053.5</b>	<b>100</b>

Source: Hoover Online Report Builder

The growth pattern of operating earnings for different segments is shown in Figure 5.2. Going forward, however, it appears that efforts are afoot to address this disparity and balance the contribution of each business segment.



Source: Cardinal - JP Morgan Health Conference Presentation, 1/12/2005

Figure 5.2: Growth of Different Business Segments

Within the pharmaceutical distribution business segment, most of the revenue is generated by the management of branded (patented) drugs. The breakup of various revenue streams is provided in Table 5.2.

Table 5.2: Distribution of Revenue Sources

Product	% of Sales	% of Profits
Branded Rx	90	65
Generic Rx	8	40
HBA/other	2	(5)

Source: Cardinal - JP Morgan Health Conference Presentation, 1/12/2005

### 5.3 Competitive Landscape

Cardinal is one of the top three distributors that control most of the drug distribution business in the United States. The drug distribution business is highly competitive and there is little that differentiates these distributors from each other. As a result, the margins are extremely low. It is important to recall that, unlike distributors in other industries, these distributors are handling drugs that are always under the threat of tampering, theft, and counterfeiting. As a result, there are very limited options available to the distributors to improve efficiency. A comparison between the top distributors is provided in Table 5.3.

Table 5.3: Competitive Landscape

Key Numbers	Cardinal Health	AmerisourceBergen	McKesson	Owens & Minor		
Annual Sales (\$ mil.)	65,053.5	53,179.0	69,506.1	4,525.1		
Employees	55,000	14,100	24,600	3,392		
Market Cap (\$ mil.)	23,883.0	6,649.6	10,538.6	1,113.0		
Profitability					Industry <sup>2</sup>	Market <sup>3</sup>
Gross Profit Margin	7.37%	3.97%	4.62%	10.24%	6.96%	48.48%
Pre-Tax Profit Margin	2.58%	1.31%	(0.41%)	2.16%	2.17%	9.87%
Net Profit Margin	1.77%	0.79%	(0.26%)	1.34%	1.44%	6.42%
Return on Equity	14.4%	10.1%	--	13.1%	14.5%	12.1%
Return on Assets	5.7%	3.8%	(1.1%)	5.3%	5.2%	2.0%

Valuation						
Price/Sales Ratio	0.34	0.12	0.14	0.25	0.24	1.32
Price/Earnings Ratio	19.46	16.05	--	18.39	18.35	20.93
Price/Book Ratio	2.79	1.58	2.14	2.42	2.38	2.49
Price/Cash Flow Ratio	15.01	12.90	210.00	14.73	12.96	11.35
Operations						
Days of Sales Outstanding	14.58	14.88	25.97	27.42	21.90	50.22
Inventory Turnover	7.7	9.5	9.6	9.9	9.0	7.9
Days Cost of Goods Sold in Inventory	47	38	37	36	40	45
Asset Turnover	3.4	4.6	4.5	4.2	3.8	0.3
Net Receivables Turnover Flow	22.5	22.1	14.2	13.0	17.6	7.5
Financial						
Current Ratio	1.37	1.34	1.27	2.01	1.40	1.41
Quick Ratio	0.4	0.5	0.6	0.9	0.6	1.0
Leverage Ratio	2.55	2.69	3.79	2.46	2.79	6.00

<sup>1</sup> Data unavailable.

<sup>2</sup> Industry: Drugs Wholesale Industry classifications are from CoreData LLC.

<sup>3</sup> Public companies trading on the New York Stock Exchange, the American Stock Exchange, and the NASDAQ National Market.

Source: Hoover Online Report Builder

## 5.4 Value Proposition

Cardinal's main objective is to help global pharmaceutical, biotechnology, and consumer health customers by:

- ☞ bringing products to market faster
- ☞ bringing better products to market
- ☞ improving the profitability of product supply
- ☞ improving returns on marketing spend

In order to achieve its goal, Cardinal is actively involved in the 'Chain of Care' – from discovery to recovery – see Appendix 3, Figure 1, to:

- ☞ improve inventory and production scheduling to reduce inefficiencies
- ☞ reduce handling and re-deploy internal capacity to other priorities
- ☞ improve process potential continuously
- ☞ seek creative tax structures to maximize after-tax income

### 5.5 Business Outlook

Despite its market leading performance so far, it appears that Cardinal's future is not on a firm footing and requires a thorough reassessment. Cardinal is facing a number of significant internal and external challenges. On the other hand, the challenges also present tremendous opportunities to Cardinal for further solidifying its position in the industry.

#### 5.5.1 SWOT Analysis: See Table 5.4.

Table 5.4: Cardinal SWOT Analysis

Strengths	Weakness
Very strong position in the market place	Business model transition
Large target group	Too aggressive in acquisitions
Diverse range of medical products and services	Over reliance on customers
	No substitute for distribution division
	Rebranding may affect profits
Opportunities	Threats
Vanity market	Reduced drug spending could affect core division
Industry characteristics	Strong competition within all markets
Partnership technologies	

Source: Pharmaceutical R&D Outsourcing strategies: An analysis of market drivers and resistors to 2010, by Steve Birch, Reuters Business Insight: HealthCare

### 5.5.2 External Challenges

The pharmaceutical industry is plagued by numerous challenges that are threatening a major overhaul of the entire industry. Among the top issues is the concern of steadily increasing drug prices. Consolidation of healthcare management organizations along with the passage of the Medicare Modernization Act (MMA) is likely to exert downward pressure on the drug prices. In addition, there is a huge push towards the use of generic drugs, which, unlike the branded drug segment, is very cost sensitive. As a result of these developments, the margins are expected to come under pressure, which will prompt the drug manufacturers to demand lower prices from distributors.

Now the drug distribution model is also undergoing a significant transformation. The traditional inflation-based distribution model is on the verge of a collapse and maybe replaced by a variety of new yet unproven models. In essence, the industry is moving towards a Fee-for-Service (FFS) model, wherein the distributors will be paid based on the services purchased, instead of a bundled service agreement in exchange for inflation-based profit opportunities.

The inflation-based model allowed distributors to generate significant returns by speculating and proper planning independent of the actual benefit of its services, but the FFS model is purely value based. As a result, the distributor's profits are expected to be lower and driven by the portfolio of service offerings. And due to the transparency of the service offerings, it is likely that buyers will select only a

subset of services, thereby further limiting returns. In other words, the changing business model will challenge the current value proposition of the distributors and put pressure on its earnings. Additionally, it is likely to create opportunities for competitors, such as UPS and Fedex, to attack the market with specialized services to grab a share of the business.

Furthermore, the growth trend enjoyed by the healthcare and pharmaceutical industry so far seems to be slowing down. The consensus opinion is that the industry will witness a slower sales growth on account of pricing pressure, despite an increase in the overall volume. As a result, drug manufacturers will be hard pressed to entertain other alternatives to improve their financial performance in the new environment. Drug distribution cost will be an obvious area to explore for reduction opportunities, advancing the case for the replacement of drug distributors with other options, such as the development of in-house capabilities, outsourcing it to UPS or Fedex, or using a 3PL provider.

In general, Cardinal is facing very strong competition in all of its business segments. Consequently, profit margins in all segments are under pressure and need constant attention. Developments in the field of information technology and medical devices are, however, offering much needed respite to Cardinal in its rebuilding efforts. Although, such new capabilities are not unique in themselves, Cardinal can compete effectively by offering a bundled suite of wide array of services to its customers,

### 5.5.3 Internal Challenges

Cardinal depends heavily on its pharmaceutical distribution and provider services division, which as noted before, generated 84% of revenues in 2004 (Form 10 K filed on 10/26/2004). For a large company, such as Cardinal, relying on the performance of a single division is a risky strategy. Furthermore, since external challenges mentioned above seem to be impacting the performance of this very division, it is even more important now for Cardinal to find other revenue sources.

A majority of the products distributed by Cardinal are sourced from only a few suppliers. This creates a real cause for concern. For example, Pfizer Inc. contributed 14% to the revenue in 2004, and collectively the five largest suppliers accounted for 40% of 2004 revenue – see Figure 5.3.

The Company obtains its products from many different suppliers, the largest of which, *Pfizer, Inc.*, accounted for approximately 14% (by dollar volume) of the Company's revenue in fiscal 2004. The Company's *five largest suppliers combined* accounted for approximately 40% (by dollar volume) of the Company's revenue during fiscal 2004 and, overall, the Company believes its relationships with its suppliers are good. The Company's arrangements with its pharmaceutical suppliers typically may be canceled by either the Company or the supplier upon 30 to 90 days prior notice, although many of these arrangements are not governed by formal agreements and therefore may be subject to earlier cancellation. The loss of certain suppliers could adversely affect the Company's business if alternative sources of supply were unavailable at reasonable rates.

Source: Form Cardinal Health Inc. 10-K filed on 10/26/2004

Figure 5.3: A Limited Supply Base

Due to Cardinal's over dependence on a few suppliers, an adverse event, such as contract cancellation, will cause a huge swing in the volume of drugs flowing in the distribution network. Additionally, internal problems at one supplier can



wreak havoc on Cardinal's network. It is easy to imagine that in such a volatile environment, process optimization is not the main consideration for a company; instead, the focus is on operational effectiveness.

A similar but bigger issue lies on the customer side as well. Cardinal relies heavily on a few big accounts, such as CVS, Novation, and Premier accounting for 35% of its revenue in 2004 – see details provided in Form 10-K by Cardinal in Fig 5.4. As indicated by Cardinal in Form 10-K, over-reliance on customers can have a negative effect on its business in case of a problem with a large customer. Consequently, business outlook of a few of clients guide Cardinal's forecasts and also make it volatile; inability to control prices is another shortcoming.

The Company's largest customer, *CVS Corporation ("CVS")*, accounted for approximately 18% of the Company's revenue (by dollar volume) for fiscal 2004 (15% relates to "Bulk Revenue," as discussed in "Management's Discussion and Analysis of Financial Condition and Results of Operations"). All of the Company's business with CVS is included in its Pharmaceutical Distribution and Provider Services segment. The aggregate of the Company's five largest customers, including CVS, accounted for approximately 34% of the Company's revenue (by dollar volume) for fiscal 2004. The Company would be adversely affected if the business of these customers were lost. In addition, certain of the Company's businesses have entered into agreements with group purchasing organizations ("GPOs"), which organizations act as purchasing agents that negotiate vendor contracts on behalf of their members. Approximately 17% of revenue for fiscal 2004 was derived from GPO members through the contractual arrangements established with *Novation, LLC ("Novation")* and *Premier Purchasing Partners, L.P. ("Premier")*--the Company's two largest GPO relationships in terms of member revenue. Generally, compliance by GPO members with GPO vendor selections is voluntary. As such, the Company believes the loss of any of the Company's agreements with a GPO would not mean the loss of sales to all members of the GPO, although the loss of such an agreement could adversely affect the Company's operating results.

Source: Form Cardinal Health Inc. 10-K filed on 10/26/2004

Figure 5.4: A Limited Customer Base

From a supply chain point of view, a distribution network designed to serve a few customers very well can't be very flexible. In case of a significant shift in the drug consumption pattern, for example decentralization, Cardinal can fall victim to its inflexibility and may not be able to make necessary adjustments quickly. The nimble competitors, such as UPS and Fedex are capable of responding quickly and take advantage of such opportunities.

Cardinal grew rapidly by acquiring a diverse set of companies engaged in a variety of businesses. For example, it acquired a number of companies recently, including Megellan Laboratories, Syncor International and Boron, Lepore and Associates. As a result, the size and the complexity of the organization have multiplied in a short period of time. Furthermore, acquisitions add value through portfolio extensions and synergy gains *only* when managed properly. In most cases, however, acquisitions result in functional overlaps, higher costs, loss of momentum, poor coordination to achieve corporate objectives, and lack of customer focus. In other words, Cardinal must manage the transition very carefully, as the corporate history is littered with examples of unsuccessful mergers and acquisitions.

To this end, Cardinal has embarked on a journey to re-brand as just one brand and one logo. Cardinal is attempting to emphasize its broad product portfolio rather than specific products or services. Indeed, integration of all new offerings into a well orchestrated complete service proposition is an extremely difficult task.

It has the potential to cause significant strategic and operational problems.

Furthermore, from the customers' point of view, to umbrella the entire company is a very bold move and one that could backfire.

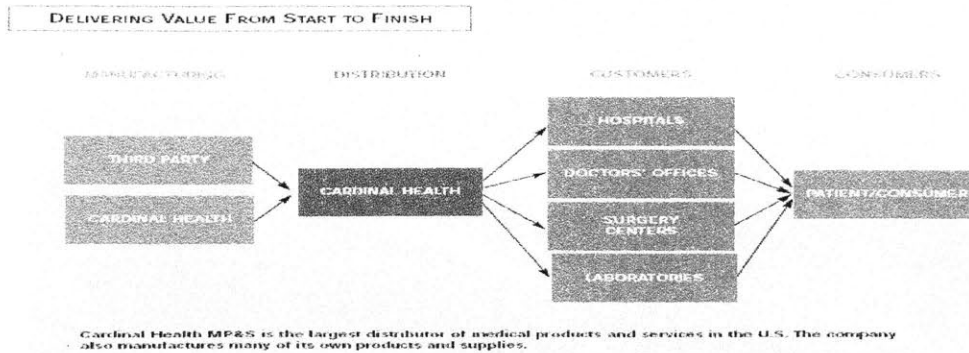
Despite the challenges mentioned above, Cardinal is in a position to grow and reaffirm its leadership by making required strategic and operational choices. The pharmaceutical industry is becoming increasingly cost conscience, a trend that favors Cardinal. Cardinal must, however, offer a unique value proposition to create a special place for itself in the reconfigured supply chain.

#### 5.6 Organization Structure

In Cardinal, the responsibility of supply chain management for the pharmaceuticals distribution falls under the ambit of two groups, namely Purchasing and Corporate Operations. The Purchasing group is responsible for procurement and inventory management, while the Corporate Operations manages operations – warehousing, pick, pack, and ship, customer support, sales administration, and the national logistics center (NLC.) These groups manage the supply chain to maintain high customer service levels.

#### 5.7 Supply Chain Operation

In principle, Cardinal is the conduit for the drug manufacturers to sell their drugs to different end customers as shown in Figure 5.5. An overview of the activities undertaken by the Purchasing and Operations group is provided below.



Source: CRM ROI Review, (2004), Volume Three, Number 3, December 2004.

Figure 5.5: Position of Cardinal Health in the Supply Chain

Purchasing, also referred to as Supply Chain Services Purchasing, is responsible for all strategic and operational activities related to purchasing including, vendor relationship management, inventory management, returns management, expired drug (morgue) management, and order processing. For a drug distributor, an efficient purchasing group is critical for various reasons, more so in inflation-based model.

As expected, the purchasing role is undergoing a significant transformation as a result of the demise of the inflation-based model. Now, the focus has shifted from seeking buying opportunities to improving forecast accuracy and obtaining better discounts, where possible. To this end, Cardinal is in the process of implementing a new forecasting tool to improve accuracy.

The Operations group is responsible for all activities starting from the arrival of the product at Cardinal's warehouse to the final dispatch to a customer location. Typical responsibilities include tasks, such as receiving, sorting, storing, and pick,

pack, and shipping. Given the sheer volume of items handled, operations function is extremely complex, which is made worse by the limited shelf life and special handling requirement of the drugs.

The Operations group handles a diverse set of problem including forward distribution center (FDC) network design, product assignments to FDCs, warehousing issues, and transportation between FDCs and customers. The transportation operations are outsourced to a 3PL provider but managed by Cardinal. With the completion of the new National Logistics Center (NLC), Cardinal is hoping for significant operational efficiencies in its purchasing and operations functions.

At present, 35% of the volume flows from the NLC and it is expected to grow further with time. The consolidation of demand from various regions is expected to make it easier for Purchasing to develop better forecasts and improve purchasing decisions. Additional benefits are expected to result from variability pooling of the consumption patterns at different FDCs.

The use of NLC, however, adds another storage location/layer to the overall supply chain. Now, instead of going directly to the FDCs, products are received at the NLC before being transferred as required. Indeed, extra handling and transportation from NLC to FDC will have a negative impact on the overall profitability, but it is expected to be off-set by the operational gains.

### *Supplier and Customer Management*

Managing suppliers and customers is a challenging proposition in the branded drug segment. Consider the supplier side first. It is difficult to manage a supplier since the supplier has all the power and there is little that a distributor can do to influence this one sided relationship. At the same time, it is easier to negotiate, if the distributor has good customers such as large hospitals and government accounts. Given the nature of the industry, it is important for the supplier to work with the distributor to reach patients as soon as possible, especially if the drug is not a first-in-class drug. Also, in due course of time, the distributors become stronger as they carry 30-35% of manufacturers' total sales, tilting the balance in their favor. The dynamics are very different for generics and OTC drugs.

The problems are very unique on the customer side as well. Selling drugs to hospitals versus a pharmacy chain present very different type of problems. In majority of the cases, the customers tend to be large and powerful organizations that demand very high level of service. In most situations, Cardinal has only a few levers to manage this relationship. On the other hand, once they build trust, Cardinal has more means to influence the customer.

### 5.8 Key Performance Indicators

The purchasing and operations group at Cardinal closely monitor the performance of various processes to maintain very high service levels. Since the

turn around time is extremely short, 10-24 hours, most of the performance measures monitor specific tasks on a daily basis.

At the same time, a few key broad performance measures are used to track the performance of the overall system to ensure that it is under control and operating as desired. The performance reports are tracked by divisions and regions to detect unusual trends in the network. A few key performance indicators tracked by Cardinal are:

- ☞ Raw and adjusted Customer Service Level trends by region and division
- ☞ Shorts with inventory by region and division (instances where warehouse system indicated availability but customer order was shorted)
- ☞ Slow moving inventory by region and division
- ☞ Daily inventory levels
- ☞ Daily inventory trends (only for turn inventory)
- ☞ Customer returns
- ☞ Morgue inventory (expired or about to expire drugs)
- ☞ Orders shipped

## 5.9 The Future

Cardinal has embarked on a strategy to reorganize its assets and to diversify into the broader healthcare market, instead of focusing narrowly on drug distribution. It is re-inventing itself into a bigger organization that is involved in more value added activities, such as manufacturing and patient related services. If history is any indication, Cardinal is expected to do well. According to Robert Walter, the CEO of Cardinal, the integration of Cardinal into a single company will be led by focused efforts to address key areas of the industry as shown in Fig 5.6.

## **A program all about focus**

---

### **Externally**

- Integrate around customers and markets
- Leverage all available Cardinal Health resources

### **Internally**

- Improve operating discipline and functional excellence
- Capitalize on our size to reduce administration costs, improve sourcing and better capture information around customers

### **Goal**

- Drive **innovation for organic, topline** growth
- Drive **synergies and productivity** for additional bottom line growth

Source: Company Presentation at JP Morgan Healthcare Conference, 1/12/2005.

Figure 5.6: Goals and Focus Areas

More specifically, the company is planning to make significant efforts in the next five years to transform dramatically-see Figure 5.7.

### ***What do we expect to look like in five years?***

- Maintain 100% focus on **health care**
- Expand market lead in **distribution**
  - Medical, surgical, lab and Rx
- Greater focus on **self-manufactured products**
  - Especially sterile Rx and differentiated med-surg products
- Greater focus on **clinical side of business**
  - Combination of Alaris/Pyxis and CSC
- Greater participation in **generic pharmaceutical** market
- Greater **international presence**

Source: Company Presentation at JP Morgan Healthcare Conference, 1/12/2005.

Figure 5.7: Future Expectations

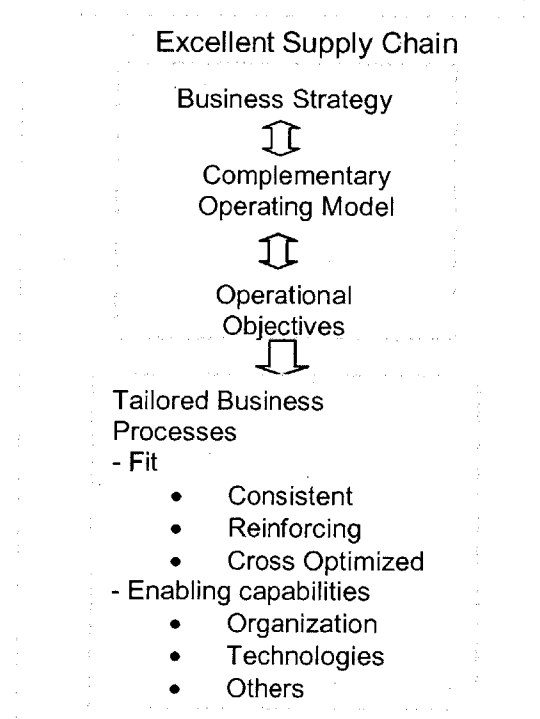
The strategy of integrating Cardinal into a single company is very similar to the successful Cisco's single enterprise system (Simchi-Levi and Simchi-Levi, 2002). Indeed, only future will tell if Cardinal succeeds in becoming a key player in the healthcare industry or not. Cardinal has shown tremendous character in the past by facing the situation head-on and adapting effectively. The challenge this time, however, is bigger and consequences more dire. Cardinal is no longer a small company that can change directions quickly to reconfigure itself and exploit available market opportunities.



## Chapter 6: The Excellent Supply Chain Framework

### 6.1 Framework Review

The definition of an excellent supply chain driving the Supply Chain 2020 project is summarized in Figure 6.1. According to this definition, the litmus test for a supply chain's excellence is its relevance to the business strategy. In other words, the supply chain processes should complement each other and resonate with the organization's overall objectives. We will use this framework to characterize supply chain practices in the pharmaceutical industry.



Source: Proceedings of the Supply Chain 2020 Project's Industry Advisory Council Q3 2004 Meeting, MIT Center for Transportation & Logistics, September 15, 2004

Figure 6.1: Excellent Supply Chain Framework

The pharmaceutical industry is fragmented, which is reflected in the design and functioning of its supply chain. There is a lack of trust among its constituents as well as a misalignment of incentives resulting in the creation of a dysfunctional enterprise. Despite all its weaknesses, however, the pharmaceutical supply

chain is successful in meeting its key objective of maintaining very high customer service level and safe custody of drugs, albeit at a high cost.

The undue complexity of the healthcare industry has also added to the overall cost, but its impact is not felt by the end users due to extensive cost shifting between multiple parties (Porter and Tiesberg, 2004). The inability of the market forces to discipline the industry can be attributed to the layers of regulations and plurality of organizations involved in buying a particular drug. Although it is imperfect, various constituents of the pharmaceutical industry make every effort to implement processes to optimize their respective objectives.

To gain an in-depth understanding of the pharmaceutical supply chain, we will use the SC2020 framework to analyze a pharmaceutical manufacturer and a wholesale distributor. We will identify key tailored supply chain practices employed by these organizations to achieve their respective business goals and evaluate their effectiveness.

## 6.2 Pharmaceutical Manufacturers – Eli Lilly and Co.

The branded pharmaceutical manufacturing segment consists of a variety of companies that follow different business strategies. For example, Pfizer has grown rapidly through aggressive acquisition supported by a large sales force to claim the number one spot, whereas Lilly has focused mainly on in-house R&D capabilities to maintain its leadership by riding a wave of innovative drugs.

On the other hand, there are companies such as Novartis that are pushing ahead by concentrating on branded as well as generic drug business segments. As a result, the operational capabilities and the business processes vary significantly. We believe that Lilly is an excellent example of a successful organization that is a pure play in the branded drug segment; it has a well defined business strategy that is supported by an effective supply chain system.

### 6.2.1 Business Strategy

According to Sidney Taurel, the CEO of Eli Lilly, the core strategy of Lilly is to “pursue products for unmet medical need.” (Taurel, 2002) Lilly is one of the leading organizations that invests heavily in R&D and in the past few years, it has successfully introduced a number of innovative drugs to the market. Lilly, unlike most other big pharmaceutical companies, is moving ahead with the strategy of investing in in-house R&D as opposed to outsourcing or acquisition.

### 6.2.2 Operating Model

The strategy of depending on innovative drugs is a “high risk and high reward” option. As mentioned earlier, due to the very low probability of developing a first-in-class drug, the research efforts spans 12-15 years with cost of introducing a new drug exceeding \$1 billion, according to some estimates. Furthermore, there is only a limited amount of time available to the company in which to recoup its investment before the patent expires. As a result, the focus shifts to marketing and promotion to maximize returns, once a drug is approved and launched.

Operations play an extremely critical role in the launch of a drug. It is operations' responsibility to ensure that the drug is available so that every possible order is captured from day one. The key constraints that make this task challenging are the availability of capacity and long lead time. The problem of capacity availability arises due to the FDA

regulations requiring certification of a site before manufacturing a drug. This lengthy approval process verifies the compliance of a manufacturing system with cGMP (current Good Manufacturing Practices) released by the FDA – see sidebar.

#### Manufacturing Issues Causing Problems

"In today's high-paced world of drug development, each day a new drug is not on store shelves can mean \$1 million or more in lost revenues. And recent events have raised those stakes even higher. Last April, the U.S. Food and Drug Administration ordered Lilly to delay production of Cialis, a new anti-impotence drug that's expected to rival Pfizer Inc.'s Viagra. The reason: FDA inspectors raised questions over quality problems in Lilly's Indianapolis manufacturing plants.

At press time, for the same reason, the FDA was also delaying the production of as many as four other new drugs in Lilly's otherwise vaunted pipeline—including the potentially lucrative osteoporosis drug Fortéo and the antidepressant Cymbalta."

Source: Glasser, P., (2002), "Case Study: Eli Lilly and Using IT to Accelerate Research Speeding Recovery," October 10, 2002, CIO Insight.

The salient characteristics of Lilly's operating model are:

- ☞ heavy investment in R&D
- ☞ heavy investment in marketing and promotion
- ☞ extensive customer support
- ☞ assurance of high drug availability
- ☞ capacity flexibility
- ☞ usage of inventory buffer (the COGS is very low in comparison to the price)
- ☞ manufacturing most new drugs in-house to assure quality and control supply

### 6.2.3 Operational Objectives and Supply Chain Network

The main objective of the supply chain management team at Lilly is to balance customer service level, cost, flexibility, and risk management to fit the marketplace needs of each product by 'pulling the right levers.' A distinguishing characteristic of the pharmaceutical supply chains is that its efficiency and performance are constrained by the design decisions taken a few years before the actual launch of the drug.

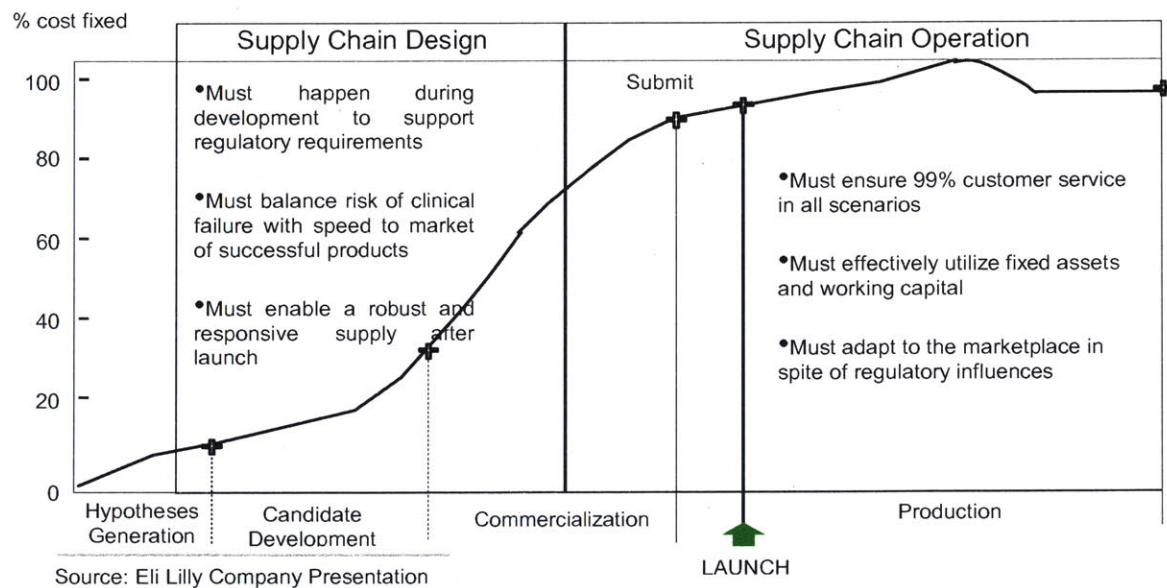


Figure 6.2: The Operating Model

As indicated in Fig 6.2, almost 85% of the supply chain cost is committed by the time the drug is launched. In other words, optimization considerations must be kept in mind a long time before and after the launch of a drug. The key objectives driving the design of the operation model are:

- ☞ must ensure 99% customer service in all scenarios
- ☞ must effectively utilize fixed assets and working capital
- ☞ must adapt to the marketplace in spite of regulatory influences

Lilly follows a two pronged approach to tackle this critical problem by focusing first on the Supply Chain Design and then on the Supply Chain Operations. Let us review these design and operation aspects in more detail.

### 6.2.3.1 Supply Chain Design

The key objective of the supply chain design phase is to manage the inherent risks by designing robust supply chains. Needless to say, the overarching objective is still to provide the highest level of customer service at the lowest possible cost. The biggest challenge at this stage arises due to the uncertainty resulting from a long horizon of around 4 years. Indeed, deciding about the capacity requirements, additions, and sourcing poses a significant challenge when the probability of success of a drug is only 20% -40% - see Figure 6.3.

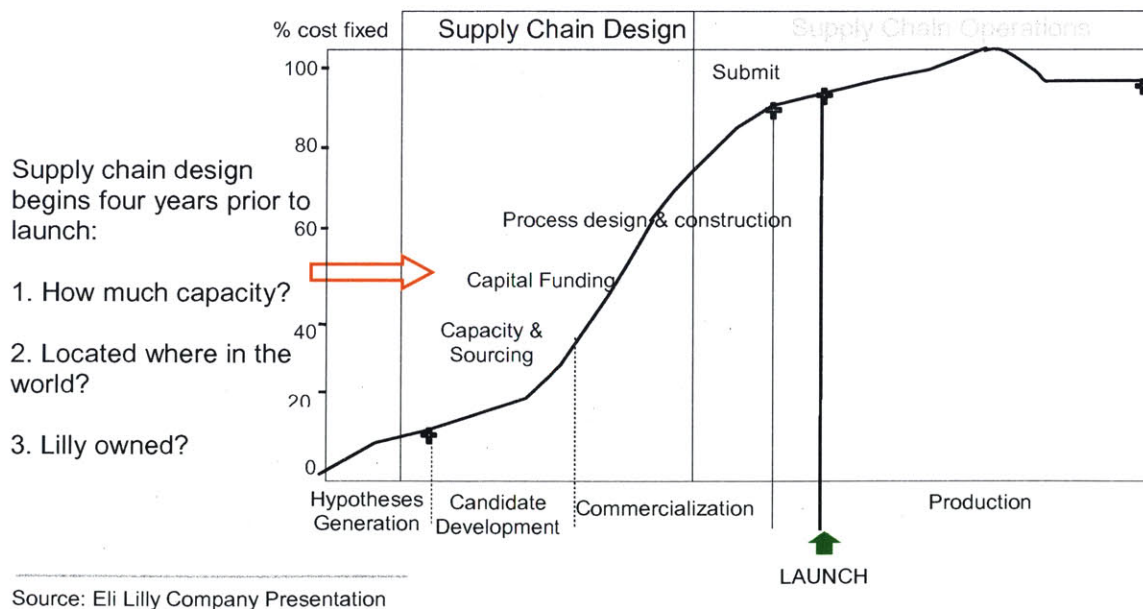


Figure 6.3: Supply Chain Design

At this stage, the chances of not launching a drug are higher than the chances of being manufactured, and forecasting demand in case of a successful launch

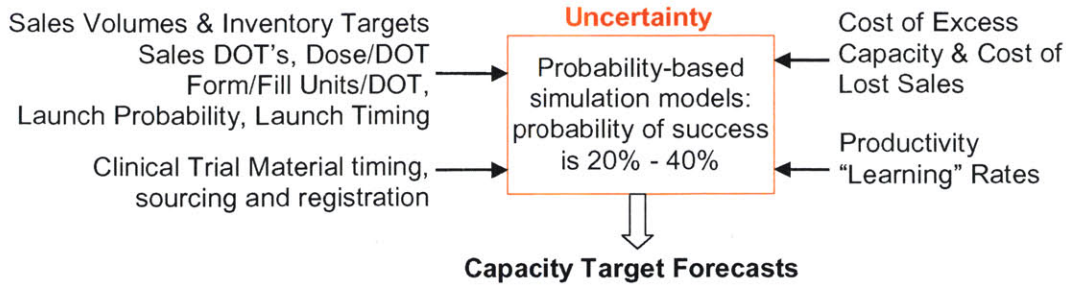
compounds the problem further. As mentioned earlier, only a handful of drugs reach the blockbuster status while others witness languishing sales. In such an environment, it is suicidal not to be able to capture every opportunity to satisfy demand, but at the same time, unused capacity is also extremely expensive.

In other words, capacity planning for a new drug in the pharmaceutical industry is an extremely difficult problem. Given the extreme demand uncertainty, highly inflexible and long registration process to add capacity, and a very short window to flex production, the designers have very limited options to address this problem. Lilly uses an effective approach to address this problem in an objective manner by following a 3 step process:

- ☞ Step 1 - Capacity Strategy and Sourcing - Global Capacity with Contingency
- ☞ Step 2 - Sourcing Optimization using quantitative analysis techniques
- ☞ Step 3 - Final decision: Can revenue be increased by using TPO?

Step 1: Capacity strategy and sourcing - Global capacity with contingency:

Details of tasks covered by this step are provided in Figure 6.4. The key idea is to find a portfolio of potential drugs that can be pooled together to develop capacity targets.



For any single molecule:

- the inputs have tremendous uncertainty
- too much capacity is too expensive
- too little capacity means missing high margin sales

**The Solution**

- Standard technology platforms for common molecule types allow the uncertainty to be managed using a "portfolio" approach.
- The agreement between development and manufacturing to use standard "kits" allows accurate modeling of total product family capacity requirements.
- The common technology groups function as "manufacturing networks".

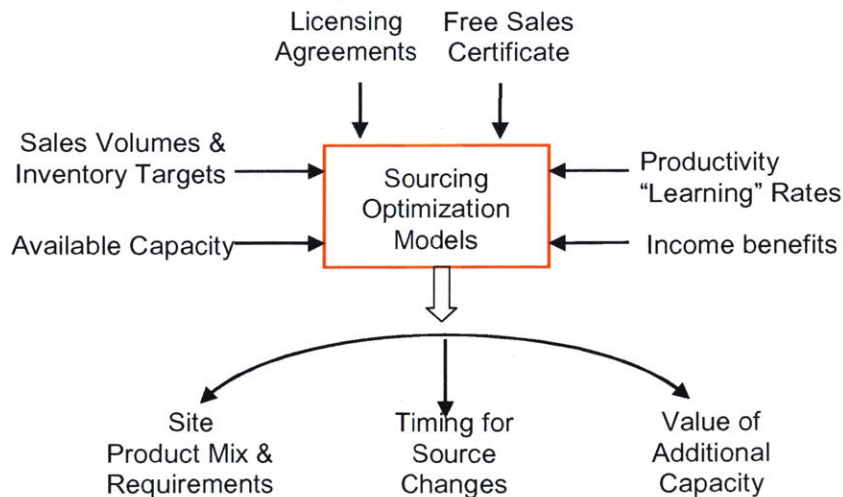
Source: Eli Lilly Company Presentation

Figure 6.4: Capacity Strategy and Sourcing Logic

Step 2: Sourcing optimization using quantitative analysis techniques:

Goal: Maximize the value of manufacturing by selecting the best product mix for

Lilly Networks – see Figure 6.5.



Source: Eli Lilly Company Presentation

Figure 6.5: Sourcing Optimization Logic



The optimization and simulation models described above are quantitative models that can't include qualitative factors, but judgment about Lilly networks influences the design of the best internal supply chain. Consequently, the quantitative decisions are augmented with qualitative considerations to develop a comprehensive design. The key qualitative factors are:

- Marketing Strategy - Location of major markets; Launch timing/sequence.
- Manufacturing technology - Processing requirements; Complexity; Learning curve; Tech support requirements.
- Health and safety - Containment level; Special hazards; Experience.
- Environmental – Permits; Impact; Treatment technology.
- Regulatory - Validation timing; Compliance.
- Financial/income benefit - Manufacturing cost; Duties and tariff barriers; Net income; Capital costs; Contingency plans.
- Manufacturing site - Fit with site mission; Available capacity; Human resource requirements; Lilly vs. non-Lilly site.

Step 3: Final decision: Can revenue be increased by using TPO?

Excellent pharmaceutical supply chain design implies optimized capital investment and maximized revenue over the life of the product. Keeping this in mind, the viability of using a Third Party Operator (TPO) is also considered before finalizing the capacity plan. The steps involved in this process are:

- ☞ manage capacity in standard technology networks
- ☞ source new products from robust and flexible sites
- ☞ utilize reliable TPOs for late lifecycle products

For most products, Lilly’s manufacturing strategy is to perform continuous Lilly capacity management (capital avoidance) via late life sourcing changes – see

Figure 6.6.

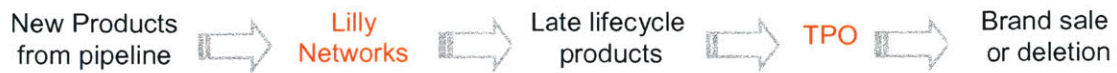


Figure 6.6: Transition to Third Party Operation (TPO)

The product is sent directly to a TPO in exceptional circumstances – see Figure

6.7.

- ☞ Special technology
- ☞ Regulatory/registration issues
- ☞ Licensing agreement limitations
- ☞ Short Time to market



Figure 6.7: Direct Transition to Third Party Operation (TPO)

### 6.2.3.2 Supply Chain Operation

The key objectives of this phase are to maintain 100% customer service level and profit maximization. The main processes involved in this phase are shown in

Figure 6.8.

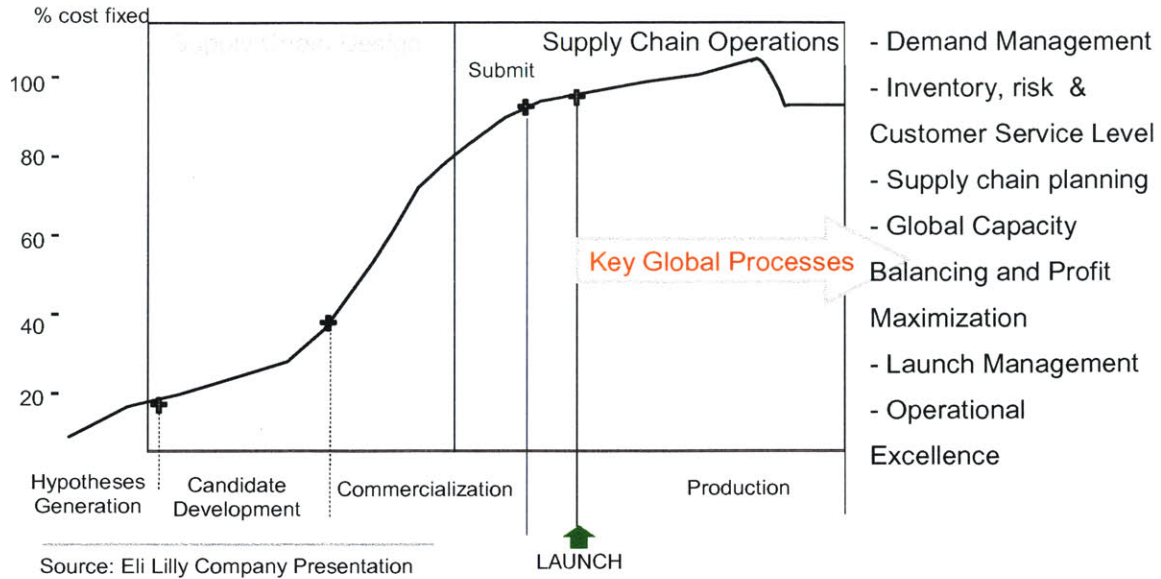


Figure 6.8: Supply Chain Operations

a. Demand Management: Supply chain operations are anchored by sales and marketing commitment to forecast accuracy. Forecast completeness and monthly accuracy – see Figure 6.9, are reviewed by the senior marketing executive committee monthly.

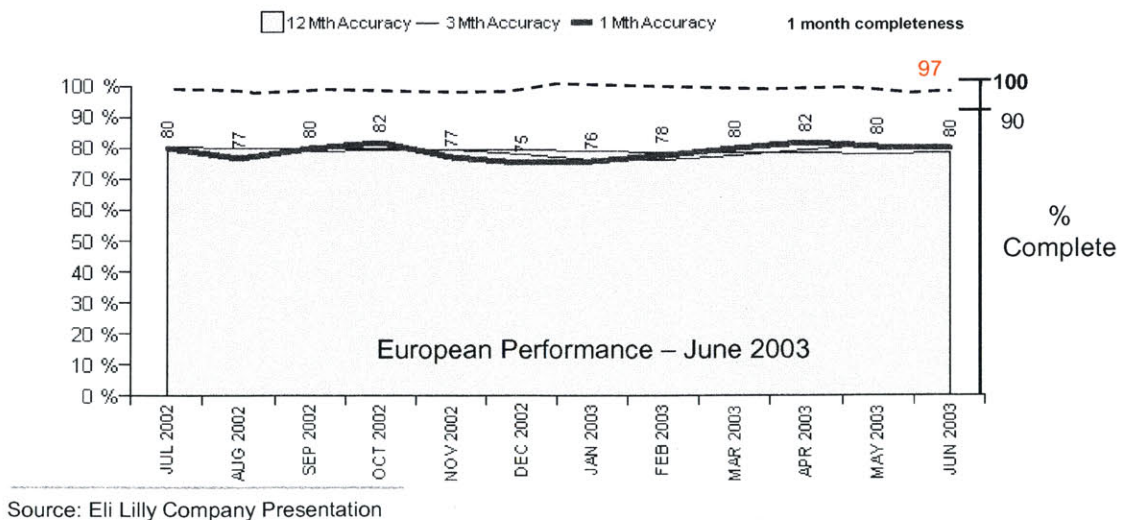
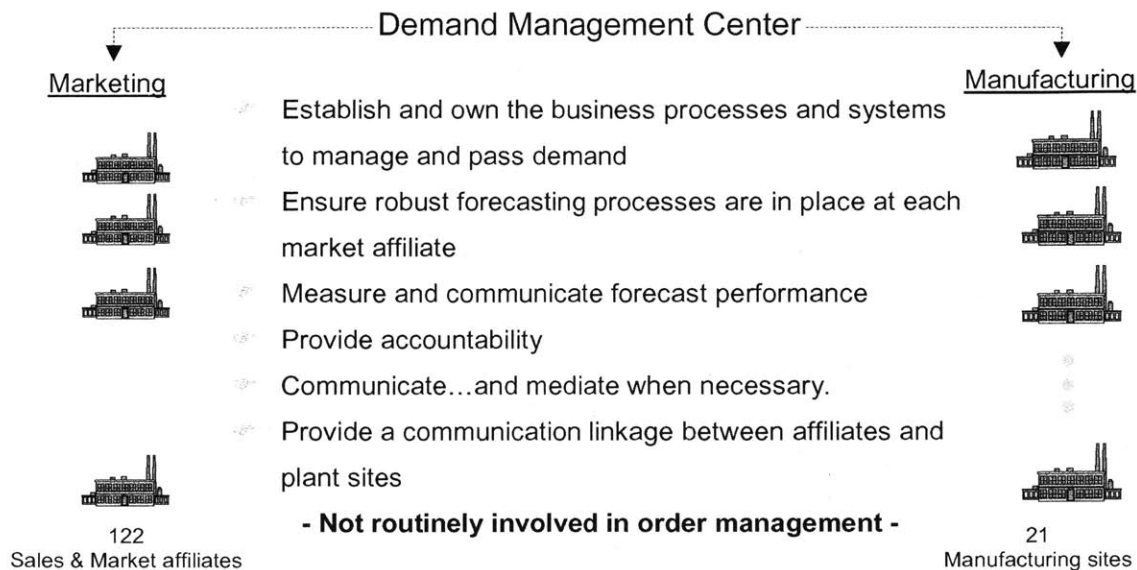


Figure 6.9: Forecast Performance: Accuracy & Completeness

## Role and Responsibility of the Global Demand Management Center

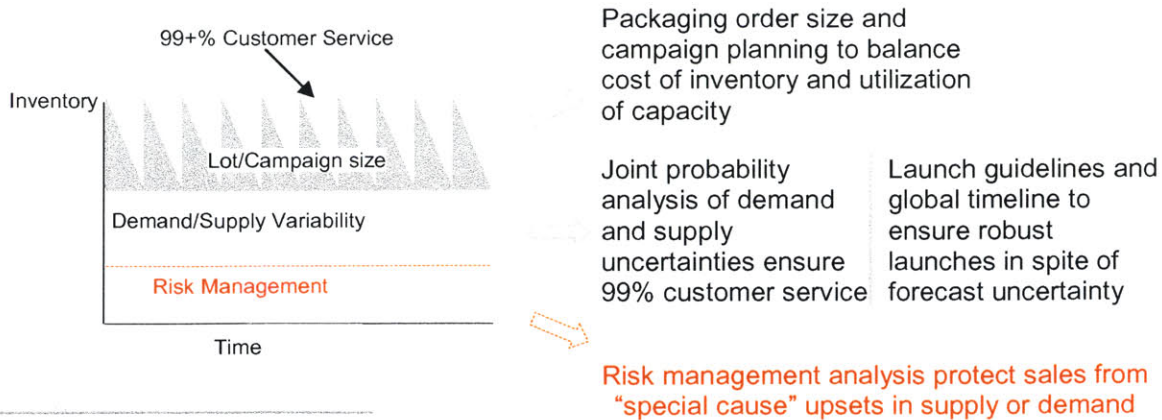
Mission: To ensure a complete and accurate statement of demand exists for all manufacturing plants. Detailed tasks undertaken by this group are listed in Figure 6.10.



Source: Eli Lilly Company Presentation

Figure 6.10: Demand Management Center Responsibilities

b. Inventory Management: Pharmaceutical financial realities demand a revenue-based approach to API and finished stock inventories. Inventory targets developed from a supply chain perspective establish the foundation for an operations plan that ensures 99% CSL in any given circumstances – see Figure 6.11.



Source: Eli Lilly Company Presentation

Figure 6.11: Inventory Management

### c. Supply Chain Planning:

Lilly runs several detailed multi layered centralized planning processes to plan supply in order to match the forecasted demand. The process is described in detail below.

*Planning Processes:* In the first quarter of each year a Long-range business plan covering the next five years is generated. This plan is based on the demand picture for new and existing products, the supply picture, the capacity utilization targets for new and existing facilities, and financial plans including expense budget and variance plans. A formal long-range capacity analysis is also run at this time, which is used as the basis for a 5 year capital investment plan.

A formal inventory plan is also established at this time based on the Global S&OP (GS&OP) analysis. All of these centralized planning activities are mirrored by a corresponding 5 year plan exercises completed at every site. The various planning processes run in parallel i.e. the central analysis and site analysis run at

the same time and then compared/adjusted to develop the final planning output. New factors are also introduced into the formal Q1 long-range exercise each year, such as refreshed set of corporate financial objectives and a formally refreshed 15 year product (demand) forecast from Lilly Market Research. Input data to this planning process include sales data in dollars and units, manufacturing finance figures (expenses, depreciation), COGS and variance, capital investment, production quantities, and inventory in dollar and units.

In addition to the long range plan, a central plan is also generated for each quarter during GS&OP. This is done both by product supply chain and by Network.

GS&OP takes a refreshed 30 month forecast from sales offices, updates the last 3 months production performance, reconsiders inventory or changes in anticipated launch dates, and creates a new plan of manufacturing for all products and all sites. The horizon for this plan is typically from 6 months to 30 months, leaving each site to do the detailed scheduling inside of 6 months.

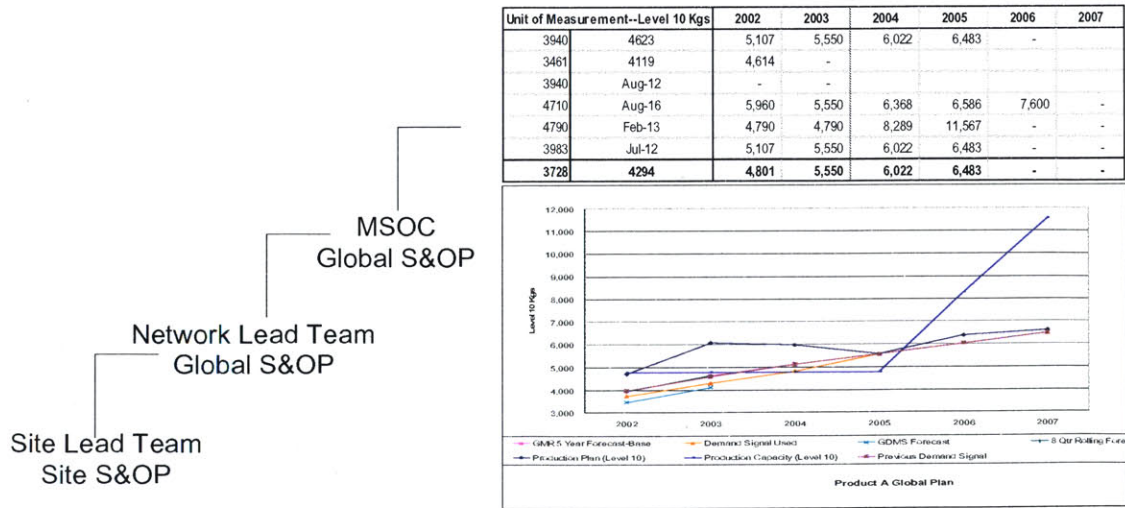
The new plan of manufacturing is built into site production plan each quarter.

Although centralized, the group completing GS&OP is made up of central supply chain and site supply chain representatives - site supply chain people are always involved in every planning process. The frequency, attendees and the objectives of GS&OP are shown in Figure 6.12.



Figure 6.12: Global S&OP process

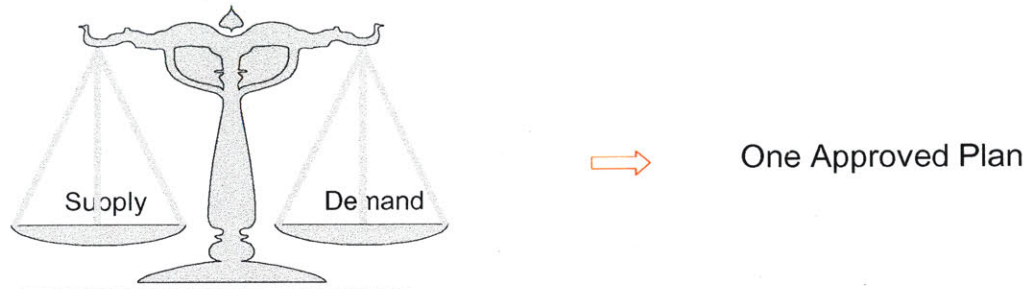
Inventory plans are developed one product at a time and the site operational plans are built for many products. The trick is to reconcile the two perspectives into a single network S&OP – see Figure 61.3.



Source: Eli Lilly Company Presentation

Figure 6.13: Supply Chain Plan – Version 1

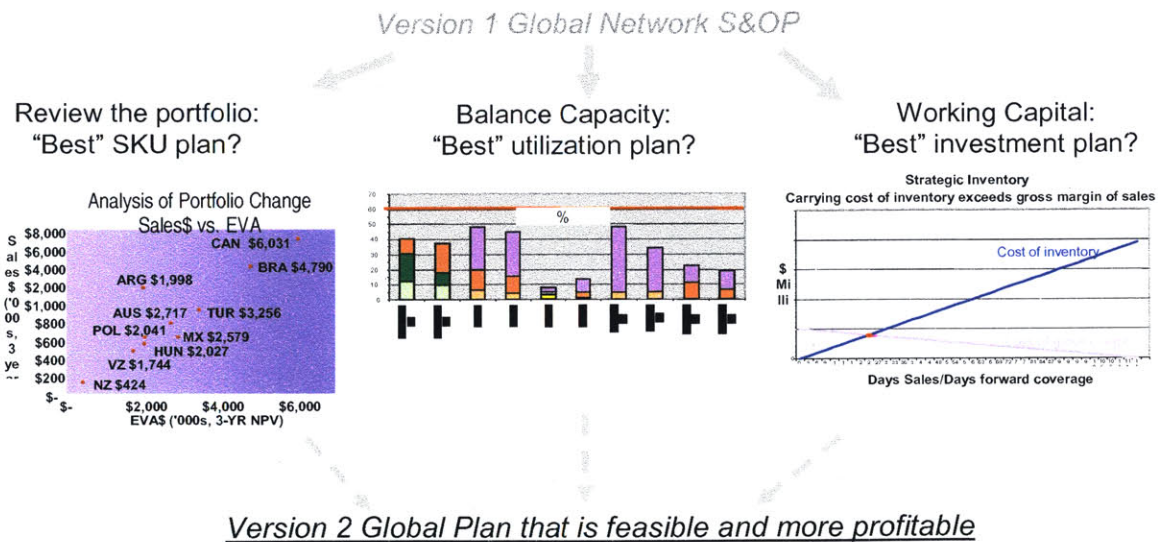
Creating one network plan, which is approved by the management and implemented at the plant, has become critical to managing the business. A Network plan, which drives the plant production plan, is executed at the shop floor of each plant in the network – see Figure 6.14.



Source: Eli Lilly Company Presentation

Figure 6.14: Supply Chain Plan Balancing

Global capacity balancing and profitability optimization: Make the doable version 1 plan better – see Figure 6.15.

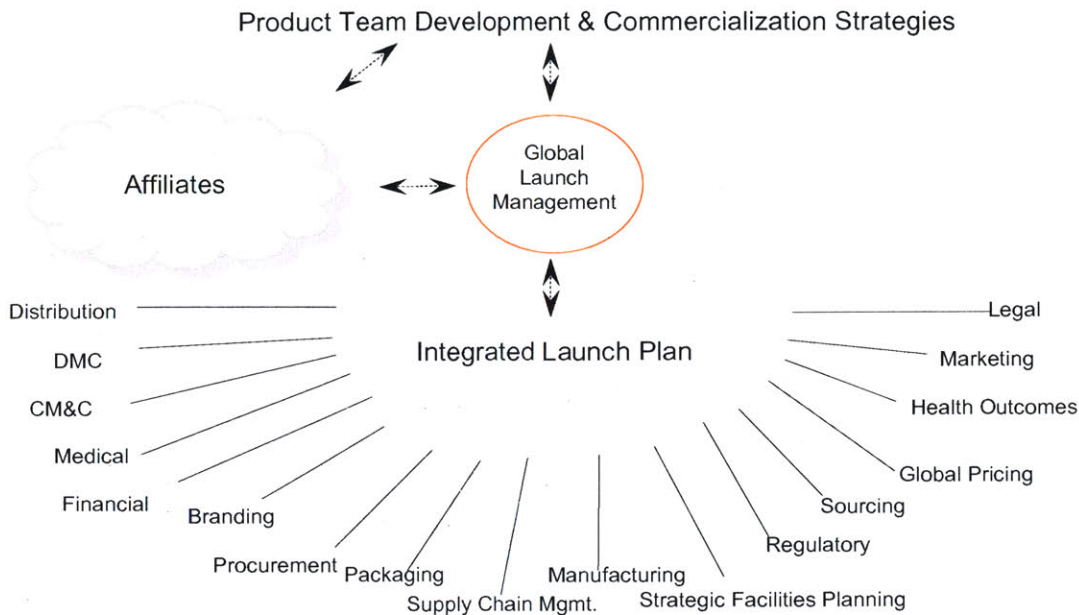


Source: Eli Lilly Company Presentation

Figure 6.15: Final Review of Version 1 Plan



d. Integrated Launch Plan: This is a single global strategy and plan that all organizations use for all supply chain related launch activities for a new drug – see Figure 6.16.



Source: Eli Lilly Company Presentation

Figure 6.16: Global Launch Management

e. Operational Standards for Supply Chain Excellence (O.S.S.C.E.): Global supply chain standards. O.S.S.C.E. Class A performance of manufacturing plants and affiliates are the foundation of supply chain at Eli Lilly – see Figure 6.17.



- ✓ Lilly's third generation of MRP II
- ✓ Standard criteria and metrics for supply chain performance
  - Criteria for factories, sales affiliates, demand management centers (and supply chains in the future)
  - Criteria includes roles & responsibilities, processes and expected performance
- ✓ Senior level consulting group to assist plants with implementation
- ✓ Annual audit is required of each site

Source: Eli Lilly Company Presentation

Figure 6.17: O.S.S.C.E. – Global Supply Chain Standards

Quantitative Benefits Realized from O.S.S.C.E. Class A at affiliates:

By implementing a monthly review of slow moving inventory:

- ☞ France prevented the write-off of 1 million euros of slow moving samples.
- ☞ Italy transferred 200,000 euros of slow moving inventory to Fegersheim to be reworked and sold.
- ☞ UK reduced slow moving inventory by 1.9 million pounds sterling.

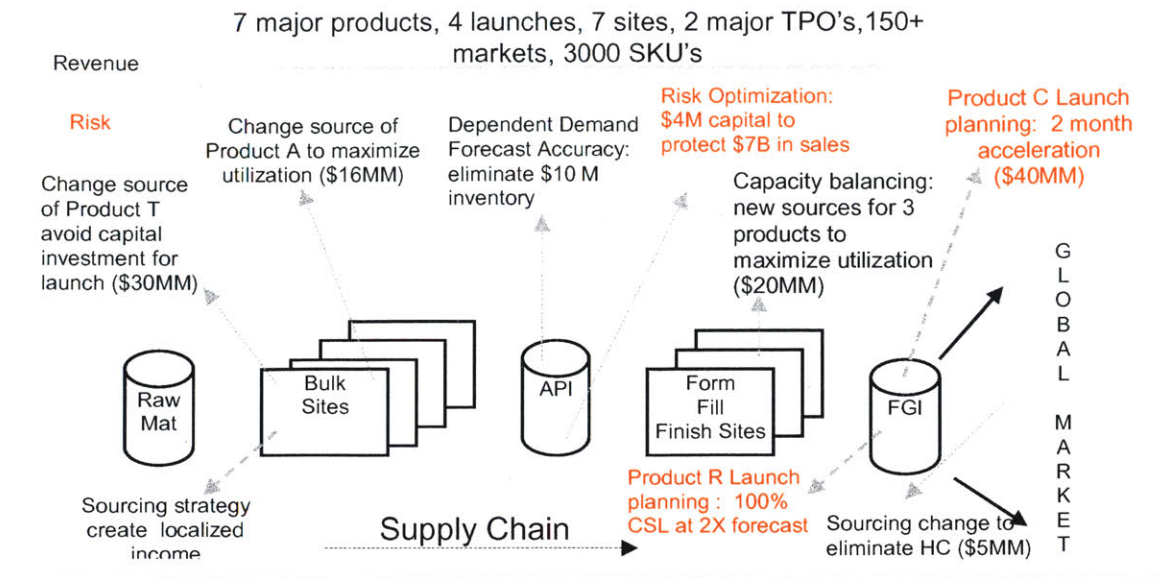
By implementing a monthly demand management process:

- ☞ Italy reduced 2004 GDMS forecasts by 44% to match financial forecasts and current market assumptions. Reducing the GDMS forecast on a timely basis freed capacity at manufacturing sites and possibly prevented the write-off of slow moving inventory at the affiliate.

By analyzing and setting inventory targets based upon OSSCE methodologies:

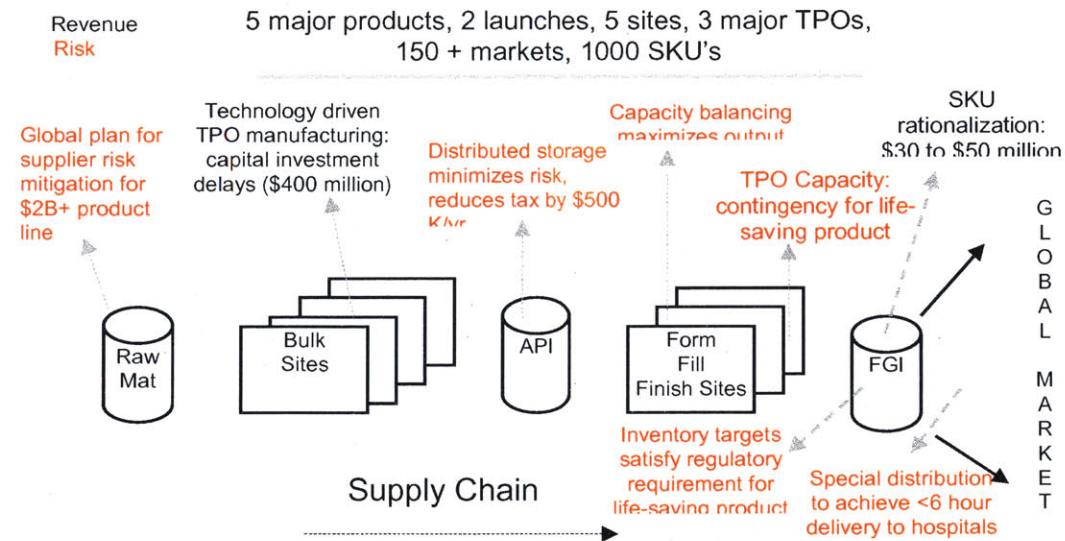
- ☞ Affiliates were setting their own inventory targets for Zyprexa and Evista. E.g. Western Europe affiliates reduced Zyprexa target by 14 DOS
- ☞ Spain reduced inventory targets by 4 million euros.

The supply chain design approach described above has been quite successful in creating robust and efficient supply chains at Lilly, resulting in significant supply chain performance gains. Two instances where definite benefits were realized as a result of this approach are detailed in Figures 6.18 and 6.19.



Source: Eli Lilly Company Presentation

Figure 6.18: Network Optimization – I



Source: Eli Lilly Company Presentation

Figure 6.19: Network Optimization - II

*Summary:* The operating model at Lilly is fully integrated into its business strategy. The four pillars of Lilly’s operating model include innovative drugs, marketing and sales, high availability, and consistent quality. Indeed, innovation is at the heart of Lilly’s business strategy as a result, their target market segment is not very price sensitive. Lilly also invests heavily to ensure that products are protected from tampering and counterfeiting.

Lilly’s operating model is focused on two metrics, namely Customer Response and Asset Utilization, with heavier emphasis on Customer Response. In Figure 6.20, we show the cause and effect relationship between the operating model, operational metrics, and business strategy of maintaining growth by offering innovative products.

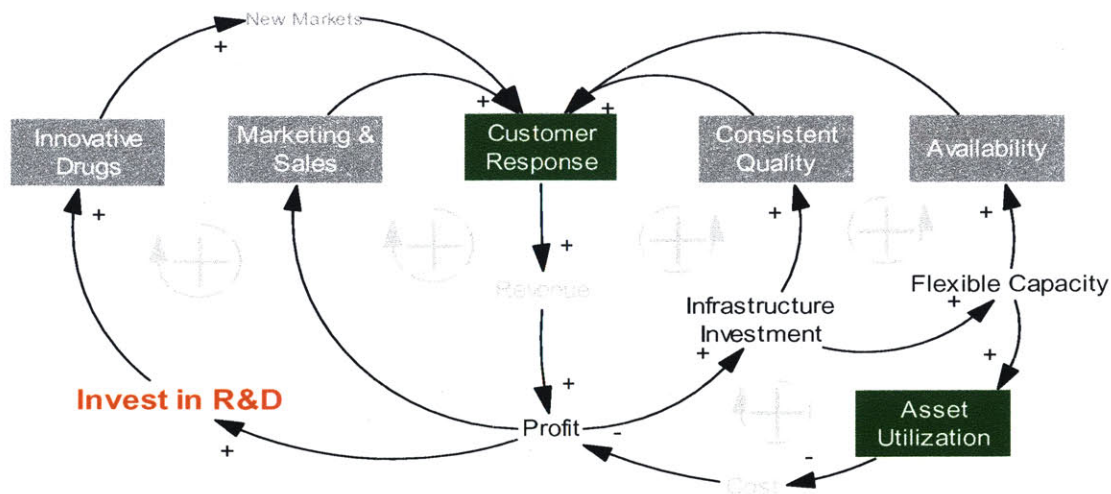


Figure 6.20: Causal Loop Diagram for Operating Model Dynamics

The key business processes enabling the operating model that drives Lilly’s business strategy are:

- ☞ Capacity flexibility – planning starts 4-5 years before a drug launch to develop “manufacturing networks” using the portfolio approach
- ☞ Sourcing optimization – make best uses of in-house and third party resources to develop an optimal plan
- ☞ Demand Management – forecast completeness and accuracy reviewed by the senior marketing executive committee monthly; “if anyone in a manufacturing plant has to create or chase demand – we’ve failed” mentality
- ☞ Inventory, Risk, & Customer Service Level - joint probability analysis to ensure 99% CSL in any given circumstance, computations also take packaging size, campaign plans, and special events into consideration
- ☞ Supply chain planning – global S&OP to create “one approved plan”
- ☞ Global Capacity Balancing and Profit Maximization – to ensure a feasible plan that reconsiders product, plant, and capital objectives and constraints
- ☞ Integrated Launch Management - single global strategy and plan that all organizations use for all supply chain related launch activities for a new drug
- ☞ Operational Standards for Supply Chain Excellence (O.S.S.C.E.) – drives process standardization across the company to maintain high quality and efficiency
- ☞ Strict quality control procedures that ensures product quality and traceability

### 6.3 Wholesale Distributor – Cardinal Health Inc.

After a period of active consolidation over the past 30 years, the wholesale distribution space is occupied by three main players namely McKesson, Cardinal Health, and AmerisourceBergen. These three distributors are responsible for handling 90% of the total distributor pharmaceuticals sales volume in the United States. Since these providers are very similar, they compete primarily on cost.

### 6.3.1 Business Strategy

Cardinal Health intends to become essential to the delivery and improvement of patient care through collaborative relationships defined by customer needs.

Cardinal maintains its competitive advantage by extending its reach upstream and downstream, beyond drug distribution.

### 6.3.2 Operating Model

Since the drug distribution landscape is undergoing rapid transformation, the affected companies haven't yet fully grasped the complexities of the upcoming challenges and opportunities. Currently, the manufactures and distributors are jockeying for position that will allow them to steer the transition in their favor.

Consequently, the operating models are in a state of flux and solutions are being implemented to quickly fill the gaps resulting from frequent urgent changes.

The situation is especially tricky because any wrong move can seriously impair an organization's ability to meet the expected service levels. As a result, the changes have to be incorporated in a very systematic and careful manner. In other words, it is very difficult for companies to develop a stable business strategy in this dynamic environment, let alone align their operating model and operational objectives to the business strategy.

Therefore, we will consider the traditional distribution model in which Cardinal thrived and rose to the top echelons of the industry to evaluate the effectiveness

of its supply chain. Recall that the traditional distribution model is primarily a buy-and-hold model. In a buy-and-hold environment, a company tries to exploit every possible buying opportunity, since most of the distributor's profit is generated by buying activities. In fact, the distributors make only a small portion of their profit directly from distribution related activities.

Indeed, the drugs purchased are not sold right away. Instead, the distributor holds the stock long enough to try to benefit from the price increase. All this while, drug expiration is a big concern for the distributor consequently, there is only a limited time window in which the drugs have to be sold regardless of the price. This dilemma faced by the drug distributor is similar to the classic problem of yield management problem. For a list of major strategic drivers, see Appendix 3 – Figure 2.

### 6.2.2 Operational objectives

Cardinal's operations are focused on two key operational metrics, namely Customer Satisfaction and Efficiency. The operating model is designed around these metrics to drive the business strategy.

*Summary:* The four pillars of Cardinal's operating model are new products and services; distribution center (warehouse) network and capacity; flexibility; and buying opportunities. Cardinal has created an effective activity system around these four pillars to execute its business strategy. In Figure 6.21, we show the

cause and effect relationship between the operating model, operational metrics, and business strategy to maintain growth by extending product and service offerings.

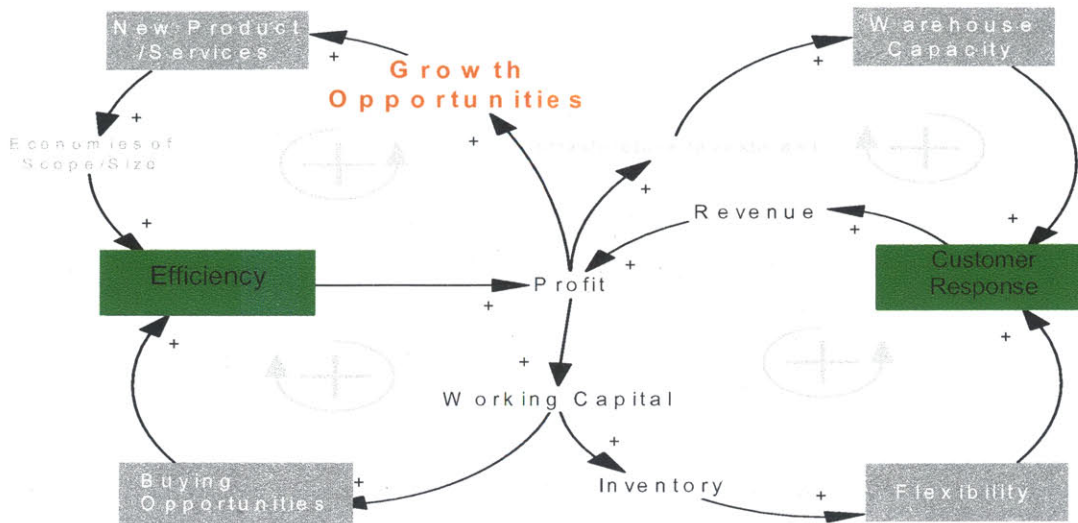


Figure 6.21: Causal Loop Diagram for Operating Model Dynamics

The key processes/aspects supporting the operating model are presented below:

- ☞ provide associated services to customers and suppliers
- ☞ strong purchasing team with seek-identify-plan-execute process for a buying opportunity (yield management)
- ☞ large warehousing network to allow storage of speculation and regular inventory to ensure high availability
- ☞ working capital to exploit unexpected opportunities
- ☞ efficient means to monitor inventory status to avoid expirations, strong sales team to sell the inventory before expiration
- ☞ flexible network system to seek opportunities anywhere in the system
- ☞ constant communication between different groups
- ☞ customer relationship management
- ☞ supplier relationship management



- ☞ heavy investment in technology
- ☞ heavy investment in infrastructure
- ☞ extensive customer support
- ☞ excess storage capacity
- ☞ flexible processes to react to sudden changes
- ☞ maintain a high level of inventory buffer to provide high service levels
- ☞ allocation of products between FDCs and NLC to maintain high service levels
  - location of push-pull boundary based on forecast availability and reliability

## Chapter 7: Synthesis and Analysis

The case for supply chain optimization is considered weak in the pharmaceutical industry. It is an industry that is driven by drug innovation and marketing. So far, we have seen that in majority of the cases, the chosen role for supply chain management is primarily operational in nature—an essential but supporting role, and not for gaining competitive advantage. At the same time, there are instances where the supply chain made a huge difference in a company— see box.

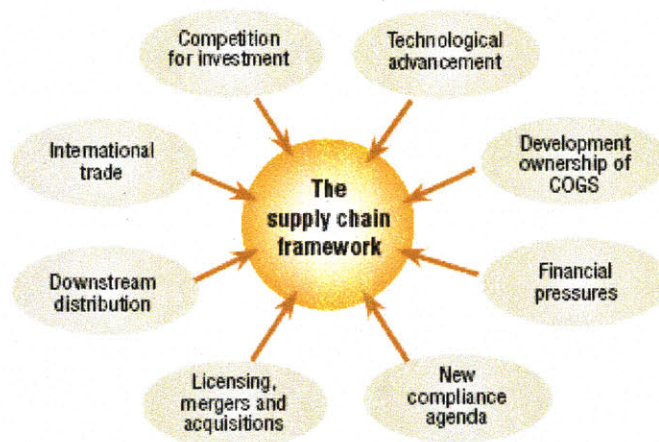
### **Rapid response to a marketplace opportunity**

The morning newspaper reported that our leading competitor was cited at last week's medical conference in Geneva for having a product that was suddenly creating negative side effects in chronic patients who had used the drug for more than six months. On Friday, the Food and Drug Administration (FDA) ordered a stop to its use until the Geneva report results could be studied, recommending that doctors use alternative treatments. Three million patients regularly used the suspended product – in the past, it had proven difficult to convert them to ours, which does not have the reported side effects. We quickly convened a meeting of the supply chain and manufacturing management teams that morning to consider how best to react to the news from Geneva and the FDA. Manufacturing could not produce enough additional products to replace its rival, but its alliance with another pharmaceutical firm could provide plant capacity to do the job. So, management placed an immediate order for large volumes. Working with marketing that night, supply chain management announced to doctors and pharmacies all over the world that additional supplies would be available within a couple of days. Overnight mail transporters, already under contract to supply individual doses of other products to patients, were told when and where to pick up the new quantities of medicines.

Within 48 hours, hundreds of thousands of additional doses were on their way into the market. Doctors had been informed about the characteristics of the drugs and pharmacies were already processing prescription changes. Within two weeks, the rival's lost business had been replaced with our product. Such quick action was possible thanks to an infrastructure created to support reliable, focused response to unanticipated changes – an eloquent, revenue-boosting example of doing business on demand.

Source: "Beyond mere survival: Pharmaceutical firms adapting and thriving, through on demand operations", IBM Consulting Services

As discussed earlier, it is easy to see why supply chain related activities are not treated as important in the pharmaceutical industry. At the same time, it was also mentioned that recent developments point to a dramatic transformation of the pharmaceutical industry. According to the CEO of Pfizer, Henry Mckinnell, “the golden age of pharma clearly lies ahead of us.” But, the weak pharmaceutical supply chain infrastructure is not ready to handle pressure from different new directions – see Figure 7.1.



Source: IBM Business Consulting Services

Figure 7.1: Supply Chain under Pressure

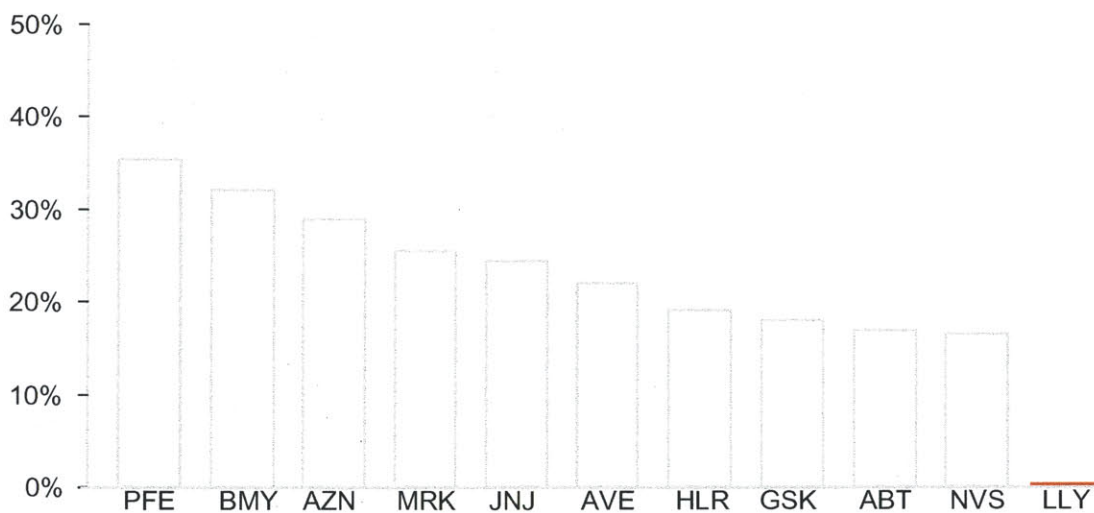
In this section, we will synthesize and analyze the information presented so far to highlight salient features of the pharmaceutical industry from a supply chain perspective. In addition, we will address some new problems faced by the industry and draw parallels with other industries.

### 7.1 Synthesis

Unfortunately, the successful past of the pharmaceutical industry is a great cause for concern today. Based on the market expectations, the EPS growth rate

should be greater than 10%, which is equivalent to a little more than 3 NCEs [new chemical entities] per year per company, whereas the average product launches per year are about 0.5 to 1.5 NCEs, according to different estimates. As result, there is a significant growth problem facing the pharmaceutical industry.

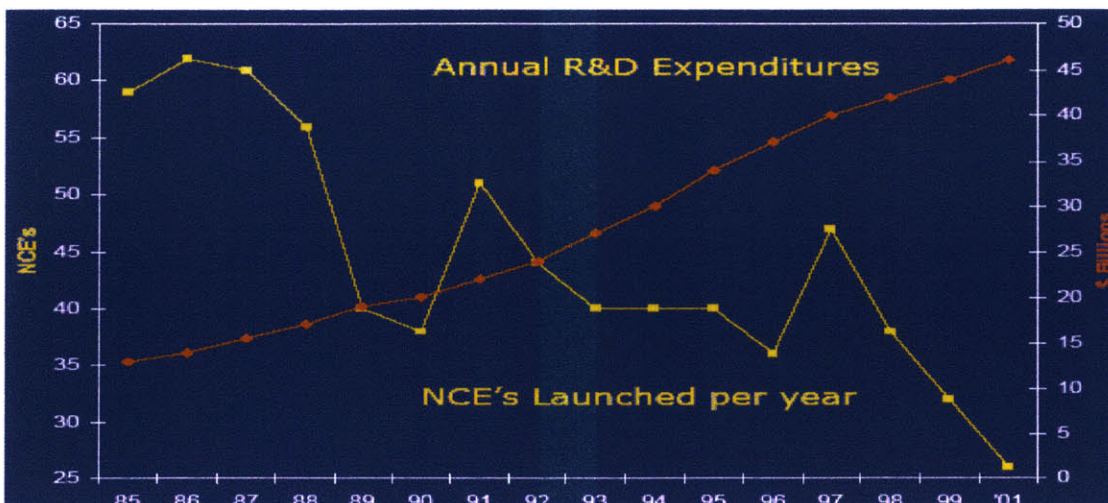
To make matters worse, there is a constant stream of drugs that are losing patent on a regular basis – see Figure 7.2, and draining the existing source of majority of the revenue. Thus, the pharmaceutical industry is under pressure to introduce innovative products from R&D pipelines onto the market at or above historical rates to replace the revenue loss resulting from generic competition.



Source: Evaluate Data ('03 sales based on partial year actuals +analyst consensus), Global Competitive Intelligence calculations

Figure 7.2: 2003 Pharmaceutical Sales Expiring (2004-2007)

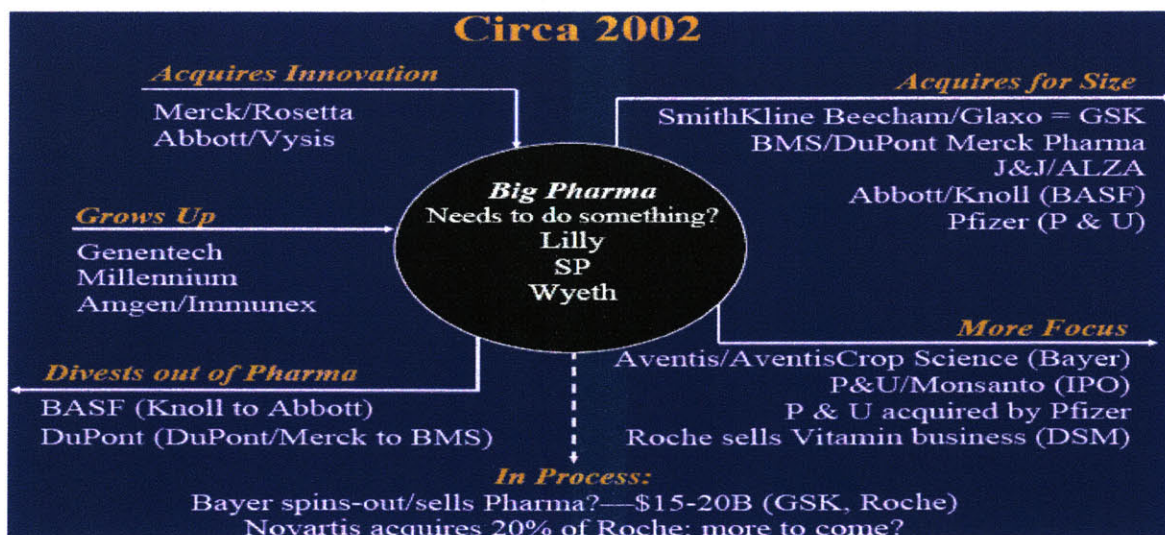
In an attempt to generate these products, R&D expenditure has risen dramatically in recent years, but the R&D productivity has gone down in the recent few years- see Figure 7.3. The traditional R&D methods and techniques are no longer effective in tackling current problems.



Source: Source: IMS/Price Waterhouse Coopers

Figure 7.3: Falling R&D Productivity

The big pharmaceutical companies are responding to this problem by unleashing a wave of mergers and acquisitions – see Fig 7.4. The primary reason for such actions is their hope that larger size will lead to better R&D productivity, which is turning out to be untrue.



Source: Burrill & Co.

Figure 7.4: Wave of Mergers and Acquisitions in Big Pharma

Furthermore, the pharmaceutical industry is a complex entity that is composed of an assortment of incompatible players. As a result, there are numerous issues that plague this industry as discussed earlier in the profile and case study sections. Of these issues, there is a set of issues or opportunities that have significant impact on the operation of the pharmaceutical supply chain. Now, we will discuss the factors that are responsible for the transformation in the pharmaceutical industry today.

### 7.1.1 Blockbuster Drug Model Failure

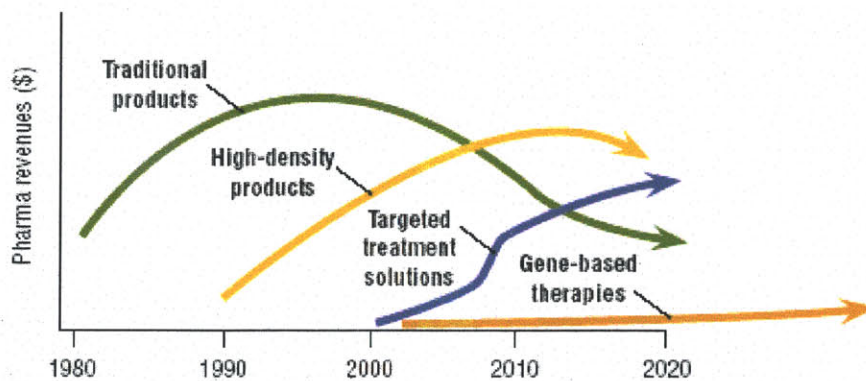
The blockbuster model is a unique feature of the pharmaceutical industry. This model, however, is unable to sustain itself and it is failing miserably. Slowly but steadily, the industry is moving away from this model for various reasons. The new directions points to the development of a wide variety of drugs with average risk and reward profile. As a result, we are likely to see a surge in the number of new drugs that may not sell as well as blockbusters. In fact, big pharmaceutical manufacturers, such as Novartis, are also investing heavily in developing capabilities to manufacture generic versions. Clearly, these developments have strategic implications on the supply chain operations – see sidebar.

#### Impact of Recalling a Block Buster

The withdrawal of Vioxx from the market, a popular treatment for arthritis and acute pain, Merck recorded \$552.6 million in charges for the quarter for unsold Vioxx inventory, estimated customer returns and costs of the recall worldwide. A study found that Vioxx, accounted for about \$2.5 billion in sales. Last month, Merck estimated that Vioxx recall would slash 50 cents to 60 cents off its earnings per share for the year.

### 7.1.2 Personalized Medicine

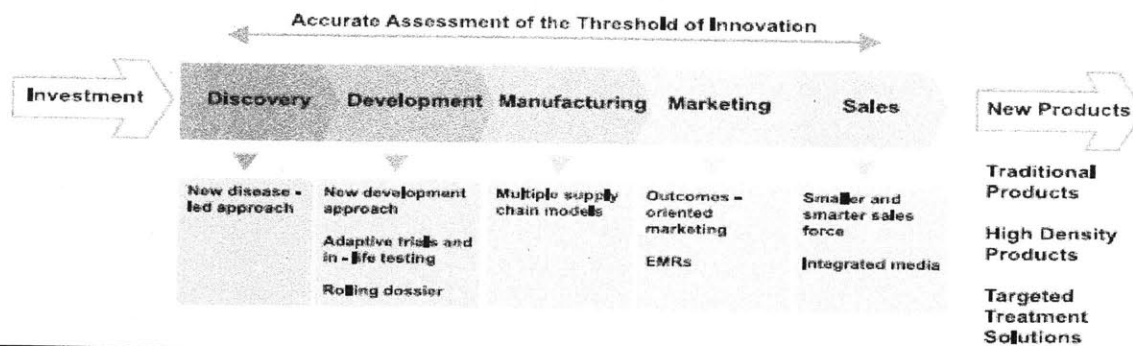
With the mapping of the human genome, significant advances have been made in the area of gene therapy. These days, a number of conditions are treated with a drug protocol that is designed specifically for the patient undergoing treatment i.e. personalized. The trend is likely to grow as we make progress using biological methods of discovery and development aimed at particular patient subpopulations – see Figure 7.5. The products will include a range of offering, such as biomarkers, preventative medicines, and treatments for patients.



Source: IBM Business Consulting Services

Figure 7.5: A Scientific and Technological Revolution in Healthcare

At the same time personalized medicine has severe consequences for the pharmaceutical supply chain. Personalized medicine will require dramatically different manufacturing capabilities and marketing strategies - see Figure 7.6.



Source: IBM Business Consulting Services

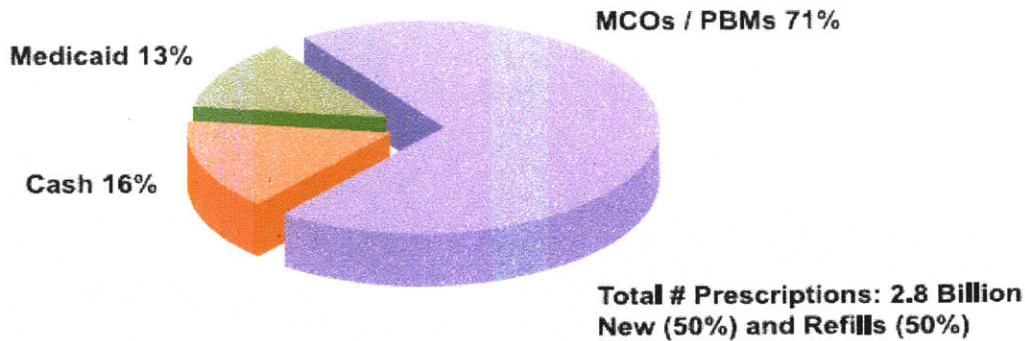
Figure 7.6: The New Pharmaceutical Value Chain

Another critical impact of personalized medicine will be the increase in the fixed manufacturing costs due to expensive process required to make biologics and simultaneous reduction in the batch sizes due to personalization. As a result, the cost of goods sold (COGS) is likely to go up. According to a study by IBM, the COGS will move from the “current average of 22 percent towards 30 percent over the next five years” (IBM, 2004b).

### 7.1.3 Rising Pricing Pressure

Due to the high risk profile of the blockbuster strategy, the ability to generate high returns is critical to its success. In the past, the market extended support to such expensive models on account of many reasons, not the least of which was a lack of collective will. Now, the tide is turning. There is an increasing pricing pressure on the manufacturers from various managed care organizations (MCO). The MCOs have grown in size and power; from 5% of insured US population in 1980 to over 71% in 2001, another 13% is managed by Medicaid, which too resembles a managed care organization – see Figure 7.7. Insurers are now refusing to pay for expensive drugs, unless justified.





Source: Pharma 2010: The threshold of innovation *IBM Business Consulting Services*

**Figure 7.7: Managed Care Dominates the Drug Market**

Consequently, the MCOs have started squeezing prices aggressively. “Eighteen states passed laws to contain rising drug costs in 2001. Florida also negotiated groundbreaking deals with Pfizer and BMS, under which the two companies have guaranteed to provide disease management programs that will save the state’s Medicaid system US\$33m and US\$16m respectively over two years. The companies have promised to make up any shortfall in cash.”(IBM, 2004a)

#### 7.1.4 Shifting Market Dynamics

During the past four-five decades, the pharmaceutical industry succeeded in launching numerous innovative drugs for a wide variety of ailments. As a result, the market now has multiple effective options for a number of conditions. Taking advantage of this market opportunity, the MCOs are using tiered formularies to control drug related costs. The members make different co-payments for different categories of drugs in the formulary. As can be expected, the co-payments increase for buying more expensive drugs. In other words, the MCOs are offering direct incentive to its members for purchasing cheaper drugs, which are typically generics.

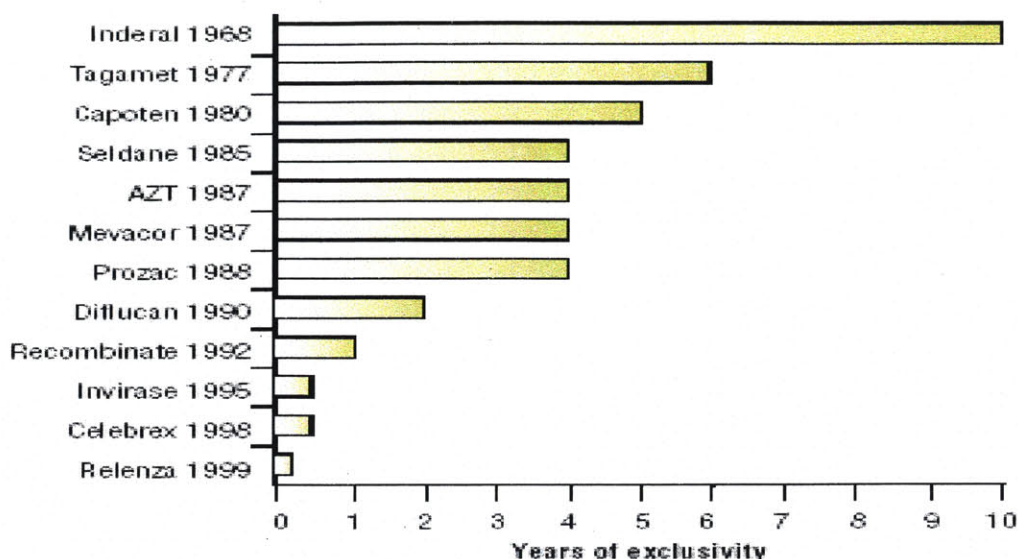
In an increasingly competitive environment, the only way a new drug can capture a large share of the market is by tapping into an unmet need, i.e. provide unique benefits that are clearly superior to the available options. This is an interesting development, since the markets, led by the MCOs, define “the parameters of innovation and determining its value in the marketplace.”(IBM, 2004a) As a result, the opportunities to make conventional blockbusters are further shrinking, for it is becoming increasingly difficult to differentiate products that treat common chronic conditions on therapeutic grounds alone.

#### 7.1.5 Generics Explosion

Encouraged by recent changes in the government policies, the generics are presenting stiff challenge to the profitability of patented drugs. The generics manufacturers are increasingly challenging the patents a few years before their expiration and exerting more pressure on the sale of branded drugs. By volume, generics accounted for 19% sales in 1984, 47% in 2000 and reaching 57% in 2005 (Bradley and Weber, 2004).

Typically, it was estimated that after patent expiration, the drug loses 80% of the volume in the first year. But for Eli Lilly, after Prozac came off patent (\$2 billion sales in 2001), 70% sales were lost within 45 days! Generics are moving in faster and shorter lifecycles for patented “first in class” products are emerging throughout the industry - see Figure 7.8, thereby reducing the years of

exclusivity from up to 10 years (for example, Inderal) down to less than one year in some cases (such as Relenza) (IBM, 2003).



Source: Beyond mere survival - Pharmaceutical firms adapting and thriving through on demand operations, *IBM Business Consulting Services*

Figure 7.8: Increased Therapeutic Competition

### 7.1.6 Rising Outsourcing Trends

As discussed previously, in R&D, the size doesn't matter. More and more, the trend is in the direction of big pharmaceutical focusing on manufacturing, marketing, and distribution, leaving the R&D to smaller biotech companies. In 2002, some of the companies were spending as much as 30% to outsource R&D. The R&D outsourcing market has grown from \$5.4bn in 1997 to \$9.3bn in 2001, representing an average annual growth rate of 14.6% (Birch, 2002). The R&D outsourcing market is predicted to grow from \$9.3bn in 2001 to \$36.0bn by 2010, representing an average annual growth rate of 16.3% (compared to an average growth in global R&D expenditure of 9.6% during the same period) (Birch, 2002).

There is a distinct trend of outsourcing the lengthy Clinical Trial activities to specialized firms known as Clinical Research Organization (CRO) – this activity grew by 70% between 1997 and 2002 (Nicholas, 2002). Pharmaceutical companies realized that managing trials is not their core competency and with the increasing demands placed by the FDA for more stringent and larger tests, it became apparent that outsourcing is a good option. Furthermore, the three phases of clinical test account for 60%-70% of the total development cost and consume a lot of time to organize trials and collect data. In face of falling R&D productivity and prices pressure, this is an obvious opportunity for improvement.

Similarly, Contract Manufacturing Organizations (CMO) are also becoming popular. It is an effective way for companies to share the risk and gain from the manufacturing expertise of the CMOs. Since there are strict regulations regarding the manufacturing process and the consequences of poor quality are severe, outsourcing manufacturing can help companies in capturing maximum value from its R&D effort.

The biggest challenge facing the outsourcing model is the mind-set of the pharmaceutical companies. Traditionally, pharmaceutical companies have looked at outsourcing as a stop gap arrangement to meet a pressing need - a short term and operational outlook. It is expected, however, that outsourcing will become prevalent and a strategic choice in the future as companies will start focusing on their core competencies.

### 7.1.7 Drug Distribution

The traditional drug distribution model, which evolved over the past 30 years, is an inflation-based compensation scheme for the distributors. The compensation of the distributors is not linked to actual services provided to the manufacturers. Instead, it is an indirect system that offers significant opportunities to the distributors to generate decent return on their investment. This model encouraged distributors to hold large stocks of inventory.

But the model is changing. The proposed structure of the new model is more transparent and eliminates the price speculation component. It replaces the inflation-based compensation with services based pricing. The new distribution model is more objective and value based, however, there is considerable confusion regarding the pricing and compensation arrangement. This change is driving a different type of buying behavior in the pharmaceutical supply chain.

### 7.1.8 Direct to Customer

In August 1997, FDA relaxed direct-to-customer (DTC) selling restrictions and around that time the HMOs also started employing formularies and discouraged direct contact with medical reps. As a consequence, the DTC spending shot up from \$791 million in 1996 to \$3.18 billion in 2003, an increase of 24.5% (Cowan, 2004). In 2002, Merck spent more money on Vioxx than was spent on Budweiser or Pepsi! (Cowan, 2004); now, there are drug ads in most prime time programming.

The wave of Direct-to-Customer (DTC) campaigns is a brand new way for the manufacturers to promote its drug. As a result, there is a significant shift in the marketing expenditure and techniques employed by industry. It has given the traditional detailing model a much needed break. At the same time, the traditional mode of selling is also undergoing changes with increasing focus on e-detailing and e-prescribing.

#### 7.1.9 Others

Other issues impacting the pharmaceutical supply chain include parallel trade, illegal sales of medicines, increase in counterfeit medicines, increasing shortages of critical medicines, and threat of terrorist attacks involving medicines. Now, the shortage of pharmaceuticals occurs more often and last longer compared to the situation a few years ago.

In summary, there are dramatic developments touching every aspect of the pharmaceutical supply chain. On the upstream side, there seems to be a breakdown of the traditional mega structures driving drug development. On the downstream side, significant changes are challenging status quo as well. It is likely that the manufacturers will move closer to the end user. Although it will allow the manufacturers to get better visibility and give more levers to manage demand, the manufacturers will encounter more variability and new problems.

## 7.2 Analysis

The recent economic downturn has exacerbated the problems of the pharmaceutical industry. Furthermore, the rapidly aging population is very sensitive to the rising cost of healthcare, driven in part by the escalation in the drug prices. Now, healthcare cost is a central political issue as well.

Consequently, the pharmaceutical industry is under tremendous pressure to justify the high prices of drugs.

The pharmaceutical industry experts, on the other hand, suggest that the true value of drugs far exceed its price. It is argued that medicines play a vital role in preventing and treating diseases. The benefits accrued by the proper use of drugs include fewer trips to the hospitals, fewer operations, and better quality of life resulting in significant cost savings. In other words, there seem to be a strong case for using more medicines, but the business of developing drugs itself appears to be sick and needing treatment. It must run more efficiently and make the best use of available resources.

### 7.2.1 Rise of Distinct Business Models

The primary structural forces that are likely to drive fundamental changes in the healthcare industry are:

- ☞ Biotechnology explosion
- ☞ Telemedicine/Internet explosion
- ☞ Rising use of alternative therapy
- ☞ Rising consumer activism

These forces are making significant impact on the underlying drivers of different aspects of the healthcare industry, such as manufacturing, distribution, pharmacy & providers, and patients – see Figure 7.9.

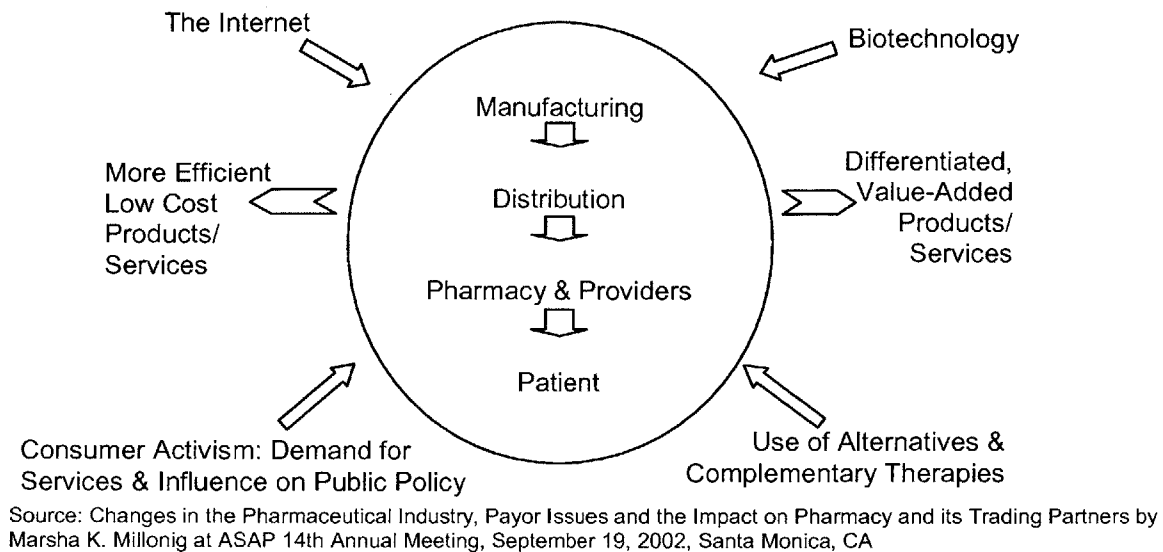


Figure 7.9: Major Forces Impacting Healthcare Industry Structure

The most significant shift resulting from restructuring will have a dramatic impact on the essence of treatment as it is delivered today, i.e., instead of treating disease, the focus will shift to prevention and move from institutions to home. Furthermore, due to the personalized nature of the medicines, drug manufacturing and distribution will become increasingly challenging. We believe that the rise in personalized medicine will precipitate the incompatibilities in the pharmaceutical supply chains that have had an uneasy coexistence so far.

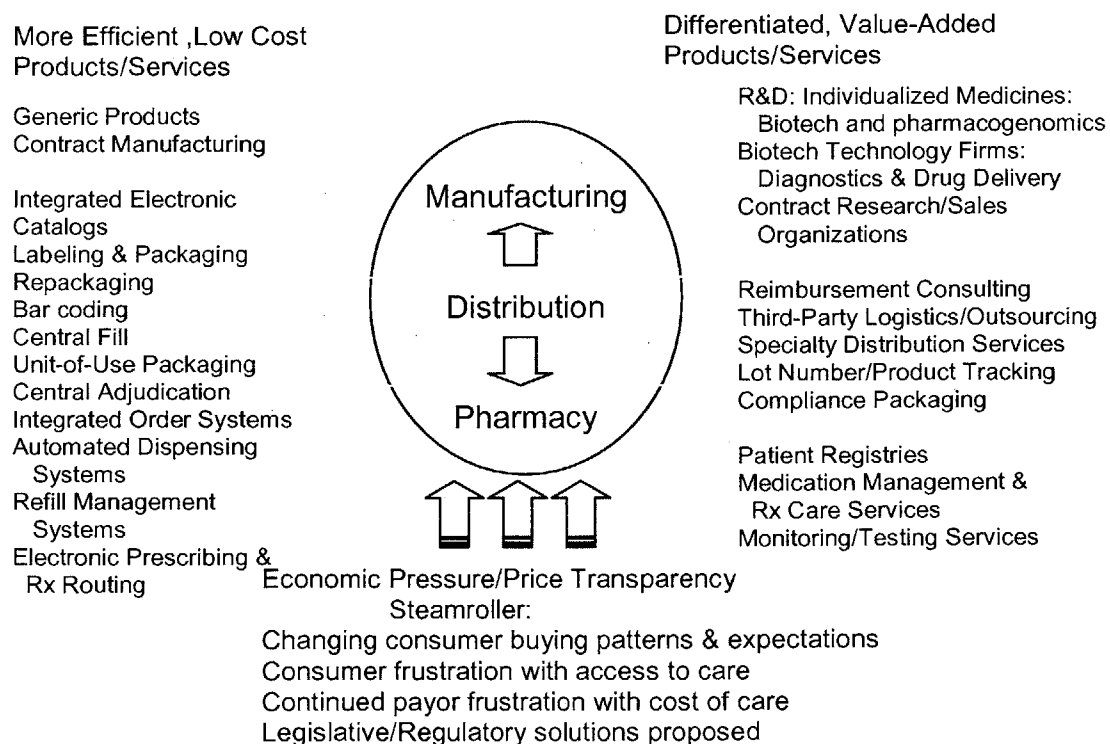
### 7.2.2 A New Pharmaceutical Supply Chain Model

The business model is the primary driver of the supply chain structure. A significant change in the business model would typically result in a corresponding



change in the supply chain structure. Fisher addresses this issue by suggesting that an appropriate supply chain design needs to incorporate the demand characteristics of the product being sold (Fisher, 1997). Accordingly, we can expect to see two separate supply chains powering the two proposed business models.

Currently, a single supply chain structure is used to distribute every kind of drug along with various health and beauty aids. But an increase in personalized medicine will lead to SKU proliferation that will be requested by individuals in small volumes from every corner of the geography. As a result, it is likely that two separate business models may take hold in the pharmaceutical industry to meet the unique needs of different categories of products – see Figure 7.10.



Source: Changes in the Pharmaceutical Industry, Payor Issues and the Impact on Pharmacy and its Trading Partners by Marsha K. Millonig at ASAP 14th Annual Meeting, September 19, 2002, Santa Monica, CA

Figure 7.10: Transformation to New Business Models

### 7.2.3 The Changing Face of Supply Chain Landscape

The four essential functions for creating a physical product supply chain include development, manufacturing, distribution, and selling. The links between these functions in the pharmaceutical supply chain are undergoing a significant transformation. We will focus on three key links in the pharmaceutical supply chain and explore them in more detail to motivate the ‘networked’ model – see Figure 7.11.



Figure 7:11: The Evolving Supply Chain

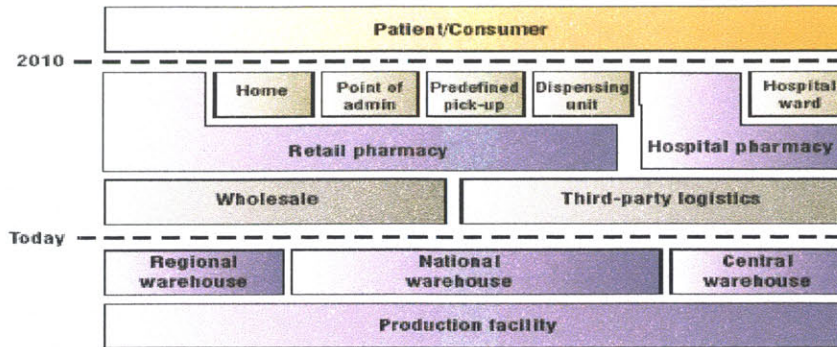
*Disintegration:* A majority of big pharmaceutical companies fully own the upstream link between development and manufacturing. Due to reasons, such as R&D productivity and product quality, a tight control is maintained on these two functions and their coordination. But now, the pharmaceutical companies are increasingly outsourcing different tasks to specialized firms, such as smaller biotech firms, CROs and CMOs to maximize productivity.

The biggest challenge to outsourcing growth, however, will be internal and not external. The companies will have to overcome their lack of trust in their partners and desire to control every aspect of their supply chain. Furthermore, most pharmaceutical companies consider research and development as their core competency and take a lot of pride in their R&D capabilities. It will not be easy for such companies to collaborate or outsource R&D to a smaller company.

*Disencumber:* The link between manufacturing and distribution is key from supply chain management point of view. At present, the wholesale distributors dominate this space and control majority of the interaction with the end customers. As a result, the manufacturers have limited visibility into the end customer demand and requirements. As expected, the buffering of the customer from manufacturer causes a multitude of problems.

“A ‘point of inflection’ is occurring in the traditional relationship between pharmaceutical manufacturers and their distributors.” (Basta, 2004) The supply contracts are moving from the buy-and-hold model (inflation-based) to the new fee-for-service (FFS) distribution model. The new model opens the doors for players, such as UPS, FedEx, & DHL that are already involved in distributing clinical-trial supplies. The ability to choose from a variety of distribution options will allow the manufacturers to become more flexible. By being more involved in the downstream activities, the manufacturers will come closer to the end customers and have the ability to manage demand and supply more effectively.

The new model will also allow the pharmaceutical companies to someday extend their sphere of influence to touch the end customer directly. Instead of stopping at the warehouse, the pharmaceutical companies will be able to integrate their systems with the point-of-dispensing system- see Figure 7.12.



Source: IBM Consulting Services

Figure 7.12: The Extended Reach of New Supply Chain

*Disintermediation:* This is an extremely important link from customer management point of view. Till recently, the pharmaceutical companies had no effective means to communicate directly with their end users. The only means to promote new drugs required labor intensive process of detailing to the medical professionals. In this sense, the pharmaceutical industry is unique that the end users have little or no say in the decision to buy a product they will consume. Indeed, there are good reasons requiring the involvement of medical professionals in the process, but it is a distinct handicap from a business point of view. With the ability to communicate with the end customer directly i.e. DTC campaigns, the pharmaceutical companies will have more levers to manage demand and drive sales.

#### 7.2.4 The Networked Model

We subscribe to the view that a 'networked' pharmaceutical model is the answer to the challenges faced by branded drug manufacturers. According to this business model, major pharmaceutical companies, "which currently operate

approximately 80% of activities in-house, will eventually perform only 40% in-house. 60% of remaining activities will be conducted externally, via a carefully selected, risk managed portfolio of straight outsourcing arrangements and strategic alliances.”(Birch, 2002) In fact, established pharmaceutical companies have already started moving in this direction. There are numerous examples where established pharmaceutical companies have engaged boutique research firms for sourcing innovative potential drugs and contracted CROs to managing trials etc.

The ‘networked’ model has distinct advantages over the traditional model. Indeed, the traditional model has served the pharmaceutical industry very well for a long time, but time has come to respond to the changing environment. In light of the new challenges facing the pharmaceutical industry, the critical capabilities offered by the ‘networked’ model are:

*Agility:* In a network community, a company can make better adjustments to respond to the changes in demand and supply. Most other industries have reaped the rewards of agility by developing networks. The auto industry serves a great example of this concept which transformed itself from a vertically integrated, 70% in-sourced company to a 70% outsourced company during the 1980s. Another example is Dell, which has acts as an ‘integrator,’ outsourcing the majority of its component manufacture and focusing on its core competency of bringing together supplier parts in a cost-effective manner.(Birch, 2002)

Although the pharmaceutical industry is fundamentally different from others, there are lessons that can be learnt from other companies to adapt few effectiveness processes. A summary of the pharmaceutical value chain opportunities that can be passed on to external companies is provided in Appendix 1-Figure 7.

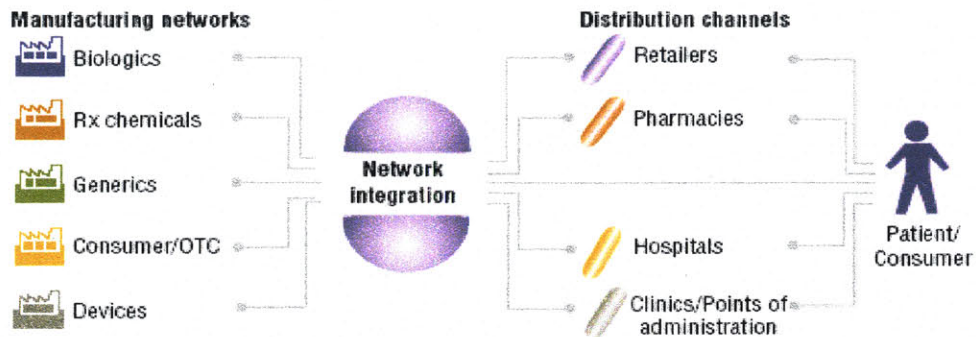
*Lead Time Reduction:* For the same reasons as stated above, a networked company has the ability to respond quickly to an opportunity or a problem.

*Rapid Market Access:* Under the 'networked' model, the companies have the ability to form or dissolve alliances with other organizations as desired; as a result, entering or exiting a market is easier in a 'networked' model. Indeed, the drive towards a fully operational 'networked' model will necessitate major changes in the current business model. The pharmaceutical companies that will choose the 'networked' model will transition into a new role that of a 'network integrator'.

*Better Resource Utilization:* A company can improve the productivity of its assets by pooling resources from other organizations.

As an integrator, instead of developing and manufacturing drugs as they do today, the primary responsibility will be to source and coordinate different expertise to fulfill demand. Such companies will create integrated supply networks by forming alliances with drug developers, clinical trial managers,

manufacturers, and distributors – see Figure 7.13. In principle, the networks will resemble the structure made famous by Cisco Systems that revolutionized the networking systems sector.



Source: IBM Business Consulting Services

Figure 7.13: An Integrated Network Model

The factors presented in section 7.1 will play a central role in the actualization of the 'networked' model. We present a framework to organize these factors and highlight their relevance and relationship to the 'networked' model.

### 7.3 A New Drug Distribution Model

The new drug distribution model has triggered an extensive debate questioning the heavy dependence of the pharmaceutical industry on wholesale distributors. It is argued that the wholesale distributors should be replaced by other options, for example direct distribution by the manufacturer or use of companies such as UPS and Fedex. But a case can be made against the replacement of the wholesale distributors.

### 7.3.1 Value Added by Wholesale Distributors

According to a study sponsored by HDMA, “current extensive services and exceptionally high service levels provided by distributors to their pharmacy customers, would add at least \$10.5 billion per year to industry costs. This is the equivalent of an 11.6 percent increase in pharmaceutical manufacturers’ total costs. This also represents 10.3 percent of the manufacturers’ revenue that distributors handle.” (HDMA, 2004) Furthermore, “if drug manufacturers chose an alternative approach of weekly pharmacy deliveries, the cost increase would be \$3.6 billion. This is the equivalent of a 4 percent increase in pharmaceutical manufacturers’ total costs. This also represents 3.5 percent of manufacturers’ revenue that distributors handle. In addition, there would be a number of other significantly negative consequences.”(HDMA, 2004)

The study also suggests that by opting for direct distribution or a 3PL provider instead of a wholesale distributor, the industry will forgo the efficiencies resulting from the consolidation of branded drugs with generics, OTC, and health and beauty aids. Clearly, managing distribution is not a natural core competency of a pharmaceutical manufacturer. As a result, the attention paid to such operations by the manufacturers will not match the tight control needed to deliver the high level of customer service expected by the customers.

### 7.3.2 Shortcomings of the New Inventory Management Agreements(IMA)

The IMAs signed by the manufacturers and the distributors are very complex. These agreements serve dual purpose of limiting the ability of the distributors to



benefit from prices increase and explicitly charging manufacturers for various services provided by the distributor. The agreements go into extensive details on how much inventory can be purchased by the distributors at any given time. The volumes are based on the sales history and the demand forecast. It tries to limit the inventory levels at the distributor's warehouse to satisfy the demand in the 3-4 weeks. There are specific rules regarding price increases etc, to eliminate opportunities for speculation.

The biggest shortcoming of the new model is that it still requires the distributor to purchase the inventory, although for a short duration. Consequently, when the inventory is purchased by the wholesaler, its value jumps up significantly since the COGS is very low compared to the price paid by the wholesaler. In other words, there is an artificial increase in the value of inventory leading to an increase in the inventory carrying cost incurred by the distributor. It is a problem for the distributor especially since they don't have any incentive to hold inventory.

### 7.3.3 The "Other" Blockbuster Model

Other industries have faced similar situations and developed creative ways to address this avoidable cost burden to the whole supply chain. One such example is the Blockbuster Video model (Cachon and Lariviere, 2005), wherein the movie studio sells a movie video to Blockbuster at a heavily discounted price with an understanding that a portion of the rental revenue will be shared by them.

In this manner, Blockbuster Video is able to buy more copies of a movie with the same amount of investment as before, and increase revenue by fulfilling more requests due to higher availability. The scheme has resulted in higher revenues and profits for both partners, along with a satisfied customer base.

The pharmaceutical manufacturer and distributor should also enter into an agreement analogous to the successful Blockbuster Video model, and develop a tiered pricing structure. The benefits and problems associated with the Blockbuster Video model are given in Table 7.1.

Table 7.1: Benefits and Issues Associated with Blockbuster Video Model

Benefits	Issues
Lower overall supply chain cost	Increased risk of expiration for manufacturer
Increase in customer satisfaction due to fewer shortages	Strategic alliance between parties is essential for this to work
Increase in revenue and more profit for all parties involved in the agreement	Manufacturer's order-to-cash cycle will become longer
Higher inventory visibility across the supply chain for better planning	Ownership and liability issues have to be resolved
Better coordination and control of the pipeline	Accounting transparency may pose problem

#### 7.3.4 Drug Distribution in the future

In light of the recent developments in the drug distribution space, it is difficult to predict the drug distribution model in the future. The likely scenarios are:

- Scenario 1: the traditional and the latest models (IMA) continue to coexist
- Scenario 2: the latest model in use (IMA) replaces the traditional model
- Scenario 3: a blockbuster video model type arrangement becomes popular
- Scenario 4: a revolutionary solution enabled by a disruptive technology

Indeed, each one of the scenario will impact the structure and performance of the pharmaceutical supply chain in a unique way. The choice of model will have a significant effect on the financial and customer service performance. A high level view of various scenarios is presented below. In Figure 7.14, we present our view of the likely developments in this space.

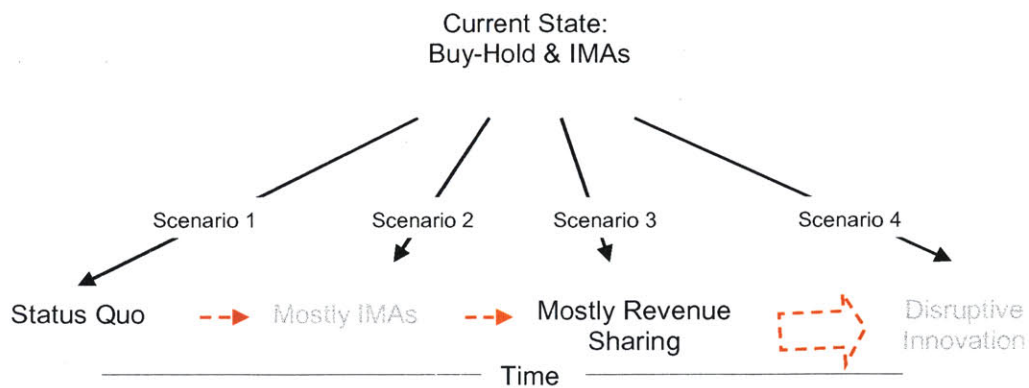


Figure 7.14: Evolution of Drug Distribution Models

*Scenario 1:* In case the two models continue to coexist, the service providers will be pulled in different direction by conflicting business strategies requiring two very different operating models – a situation they are faced with today. In the traditional model, speculative buying and holding excess inventory is best, whereas IMAs won't allow hoarding of inventory and encourages a lean operation. In such a scenario, it is difficult to employ a structured approach to redesign and operate the supply chain using standard policies. In other words, this scenario represents a state of confusion for the distributors. Indeed, such dilemmas can be commonly found in other industries as well, but companies have not been very successful in balancing such contradicting models.

One such example is the airline industry. At present, there are two very different operating models prevalent in the airline industry, namely, the hub-and-spoke model utilized by the biggest carriers, such as American Airlines, United Airlines etc. and the point-to-point service model made famous by low cost carriers, such as Southwest Airlines, Jet Blue etc. The two models are very different from each other at many levels. In 1994, Continental Airlines launched low-cost airlines-within-an-airline to compete with Southwest Airlines. And we know the result. In fact, there was a deterioration of service in both segments.

A recommended approach in this situation calls for separation of the two operating models and creation of two parallel supply chains. The two entities will be designed to exploit the opportunities presented by different contractual arrangements with the manufacturers in the most effective manner. The recommendation follows analogously to the concepts presented by Fisher(Fisher, 1997). In this case, however, instead of actual product demand characteristics, the industry dynamics will drive the separation of the operating models. Indeed, there will be many common touch points between the two supply chains at the operational level that will produce economies of scale and scope as enjoyed today by big distributors.

From the manufacturer's point of view they have a choice to make as well. The nature of the constraints with the most crippling effect will influence the preference for a distribution models. The key issues facing a large manufacturer

include control, regulations, accounting practices, and cost; the medium and small manufacturers are driven more by cash flow, and cost concerns. In addition, large manufacturers enjoy power to dictate the terms with the distributors as compared to the medium and small manufacturers. Hence, it appears that the most of the large manufacturers will opt for the IMAs, where as most of the medium and small manufacturers will gravitate towards the traditional model.

It will be very difficult for the big distributors to exit the competition due to lucrative opportunities to make good profit. At the same time, the stricter and less profitable arrangements with the large manufacturers will continue to pressure the distributors.

*Scenario 2:* From the point of view of total supply chain cost, this scenario appears to be the most expensive option. It will also make the supply chain more rigid and restrictive. The big 3 distributors will continue to dominate the space. The market forces will not be able to drive efficiency and a constant struggle for margins will plague the relationship between manufacturers and distributors. In this case, it will be difficult for the big 3 distributors to decide between staying and departing. A very likely outcome is that after some time, this model will gradually transition into Scenario 3.

*Scenario 3:* This scenario offers tremendous opportunity to the partners for developing creative schemes to boost their revenues and margins. This scenario will witness a proliferation of distribution service providers, consequently, the dilution of the market share of the big distributors. The power of market forces will rationalize the competition and the supply chain costs will decrease. This scenario is likely to witness the fragmentation of the distribution service provider base, leading to localization of the competition. The best option for the big distributors in this case will be to exit the market, instead of competing with numerous players in this space. The big distributors could benefit more by targeting other lucrative business opportunities available to them due to their healthcare expertise and availability of ready cash.

*Scenario 4:* Implications unknown!

#### 7.4 RFID - Technology to the Rescue

Technology is the key driver of major transformations in any industry. A particular technology, namely RFID, is promising to usher in a new era of hope in the pharmaceutical industry. There is a natural fit between the needs of the pharmaceutical industry and the capabilities of RFID technology. Specifically, RFID technology will address the following unique issues:

- ☞ alleviate concerns arising from drug counterfeiting
- ☞ track and trace purity and accuracy of ingredients
- ☞ track and trace recalls to ensure proper disposal
- ☞ manage returns which is a significant problem

## **Chapter 8: Conclusion**

In this study, we investigated the complexities of the pharmaceutical industry to identify excellent supply chain practices. In particular, we focused on the patented drugs sold in the United States. To define excellence, we used the description adopted by the Supply Chain 2020 project. According to this definition, a supply chain is excellent if it enhances the business strategy. In principle, therefore, every successful company is likely to possess an excellent supply chain. Even though the pharmaceutical industry lags other industries in the application of sophisticated supply chain tools and techniques, leading pharmaceutical companies have executed their business strategies effectively by using well crafted supply chain practices.

We carried out a literature review and completed two case studies involving Eli Lilly and Co. and Cardinal Health Inc. We studied the financial structure, supplier/customer idiosyncrasies, latest trends, and issues to characterize the pharmaceutical industry. The analysis of this information allowed us to develop a comprehensive understanding of the underlying industry dynamics.

Based on our investigation, we conclude that Lilly and Cardinal, both have excellent supply chains. It should be made clear that, in isolation, most of the practices followed by these companies are basic in nature and in vogue in other industries for a number of years. The success of their supply chain system is primarily due to the tight “fit” between the supply chain processes and the

business strategy. The integration has resulted in effective operating models that resonate with the respective business strategies.

The biggest challenge faced by a patented drug manufacturer is the uncertainty associated with the launch of a new drug. As a result, forecasting demand poses a significant challenge for the supply chain planners. To make matters worse, adding capacity at a short notice is not easy due to government regulations which can take anywhere from 2-4 years. Consequently, capacity planning takes a center stage in tackling the challenge of demand uncertainty.

An effective solution to manage the capacity issue in the pharmaceutical industry is to build capacity flexibility. Lilly has done a wonderful job in deploying their assets effectively by using the concept of “manufacturing network.” In simple terms, a manufacturing network is a group of plants that is registered for manufacturing multiple products that share similar manufacturing process. By practicing this concept, Lilly has been able to hedge against the launch uncertainty and also protect against the volume uncertainty. Indeed, this strategy increases the complexity and cost of the system, but the benefits far outweigh the additional cost.

As a distributor, Cardinal is faced with a challenging environment consisting of demanding customers and powerful suppliers. Due to the nature of their role, there is a big difference between the strategy drivers of a manufacturer and a



distributor. For a distributor, operational efficiency is at the core of its business strategy. Cardinal's success can be attributed to its ability to execute business processes efficiently. So far, Cardinal has excelled at consolidating demands and supplies across its various customers and suppliers to benefit from economies of scale and scope. Its laser sharp focus on customer satisfaction has allowed Cardinal to win and retain big accounts thereby further improving its operational efficiency due to new consolidation opportunities.

In our opinion, in general, the pharmaceutical industry is ailing. Each component of the pharmaceutical supply chain is under pressure to change. To make matters worse, the public opinion is also very negative and critical of the pharmaceutical industry. The major problems facing the pharmaceutical industry include pricing pressures, lack of R&D productivity, ineffectiveness of the blockbuster drug model, and explosion of generics. In addition, the drug distribution model is also under fire. Consequently, the pillars of the traditional business model are disintegrating fast. An important parallel development that will complicate the situation is the growing interest in personalized medicine.

The transformation of the pharmaceutical supply chain is under way. The popularization of personalized medicine is likely to trigger dramatic changes in the traditional pharmaceutical business model. The industry will have to adjust to a new way of doing business in light of targeted medicine's need for smaller batches of numerous SKUs. Over a period of time, the pharmaceutical industry

will move from a mass production environment to a batch production environment. Contrary to the notion of process evolution, the industry will move towards unit production as the field of personalized medicine matures. Indeed, this will be true only for a subset of treatment protocols, since many conditions, if not most will continue to respond positively to the traditional approach. As a result, we will witness the launch of parallel business models to manage different types of drugs, in turn requiring separate supply chain structures.

The new pharmaceutical business model taking shape is very similar to the network model made famous by Cisco. We believe that a 'networked' pharmaceutical supply chain will perform effectively in this uniquely constrained industry. The network model will leverage the highly specialized knowledge of various players in different segments of the supply chain to create a powerful virtual entity. It is likely that the big pharmaceutical companies of today will migrate into the role of a network integrator. In other words, the big pharmaceuticals will focus solely on marketing and selling, instead of developing and manufacturing drugs.

Lastly, the entire drug distribution segment of the pharmaceutical industry is under a serious threat of disintegration. Based on the latest developments in this area, it appears that there is a lot of friction between manufacturers and distributors. The new inventory management agreements, which tout the fee-for-service paradigm, are also falling short of making a dramatic impact on the

pharmaceutical supply chain efficiency. We believe that a lot can be learnt from the Blockbuster Video model to make the whole channel more profitable.

According to this model, the manufacturer should sell the drugs to the distribution service provider at a very low price – close to the actual cost of making a drug – and enter into a revenue sharing arrangement to make up for the revenue shortfall.

The pharmaceutical industry has performed very well historically, but the model is no longer effective. The underlying dynamics of the industry are shifting and consequently, the pharmaceutical companies should respond by redefining their business strategies along with developing brand new operating models.

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## Appendix 1

Salient features that make the pharmaceutical industry unique are as follows:

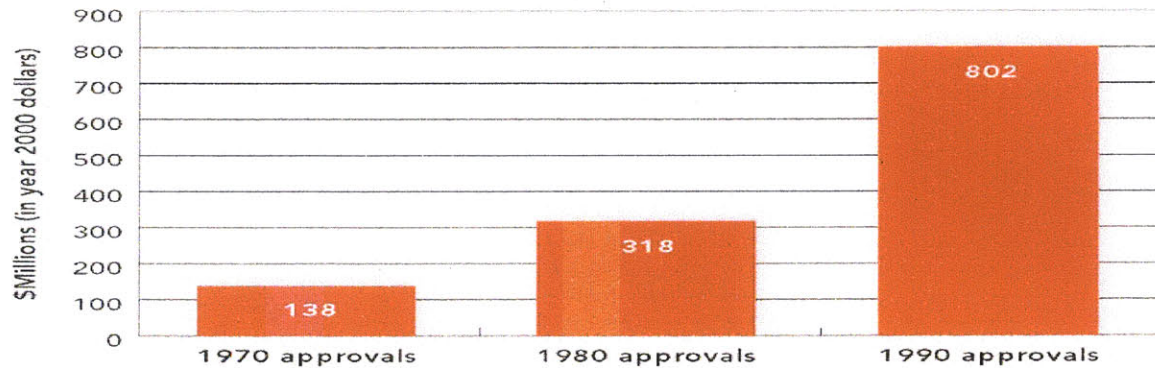
- ☞ highly regulated
- ☞ on an average, only 1 out of 5000 medicines is approved for patient use<sup>1</sup>
- ☞ the average cost of bringing a new medicine to market is \$802 million – see Figure 1
- ☞ the average development time for a new drug ranges from 12-15 years<sup>1</sup>
- ☞ on an average, only 30% of the drugs make money<sup>2</sup>
- ☞ prescription drugs account for 10.5% of the total health care cost<sup>3</sup>

1. Dimasi et. al., "Phase transition probabilities and durations," Tufts CSDD

2. Grabowski et. al. (2002), "Returns on Research and Development for 1990s New Drug Introductions," *Pharmacoeconomics* 20, suppl 3Developments

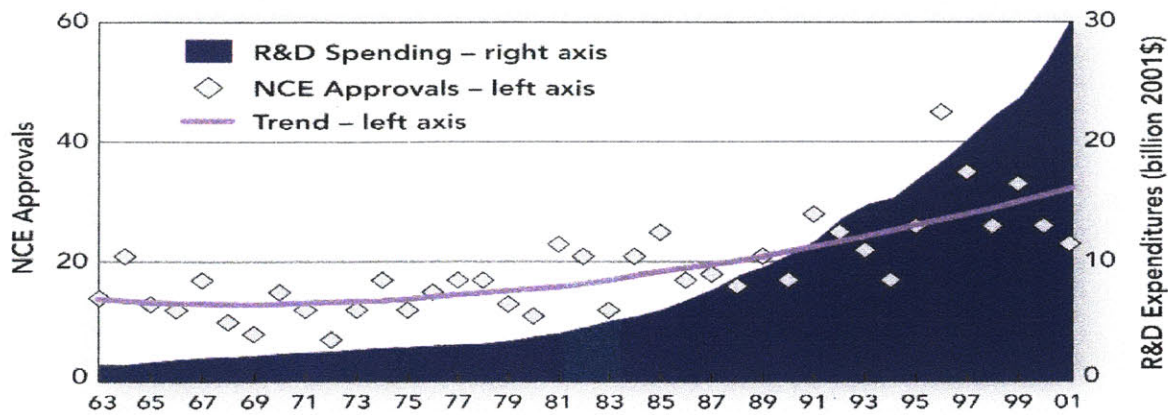
3. Pharmaceutical Industry Profile 2004 (Washington, DC: PhRMA, 2004), [www.phrma.org](http://www.phrma.org)

Figure 1: Salient Features of Pharmaceutical Industry



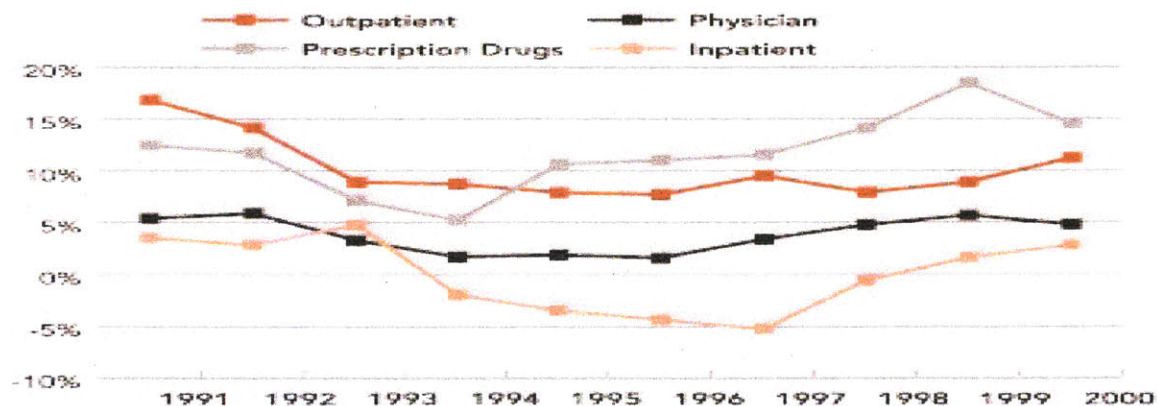
Source: Tufts Center for the Study of Drug Development

Figure 2: Average Cost to Develop a New Drug



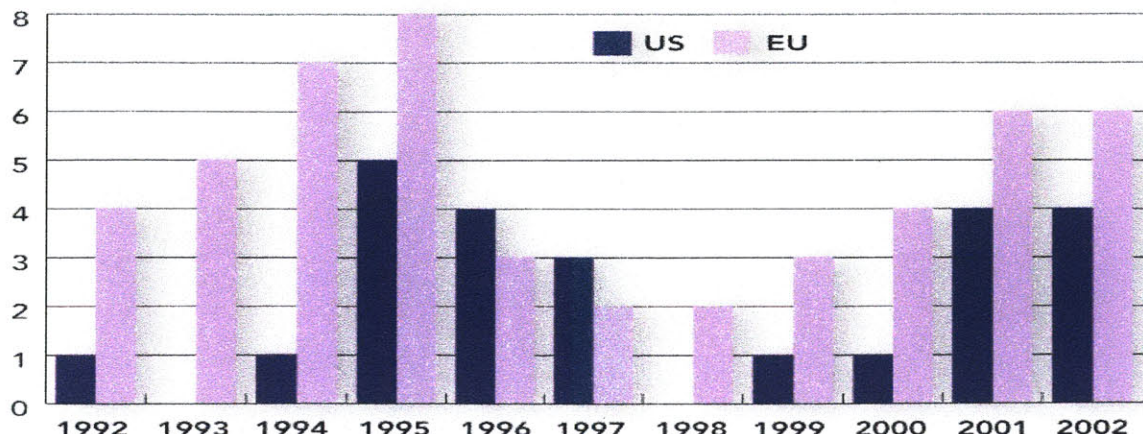
Source: Tufts Center for the Study of Drug Development

Figure 3: R&D Productivity



Source: Milliman USA Health Cost Index Survey

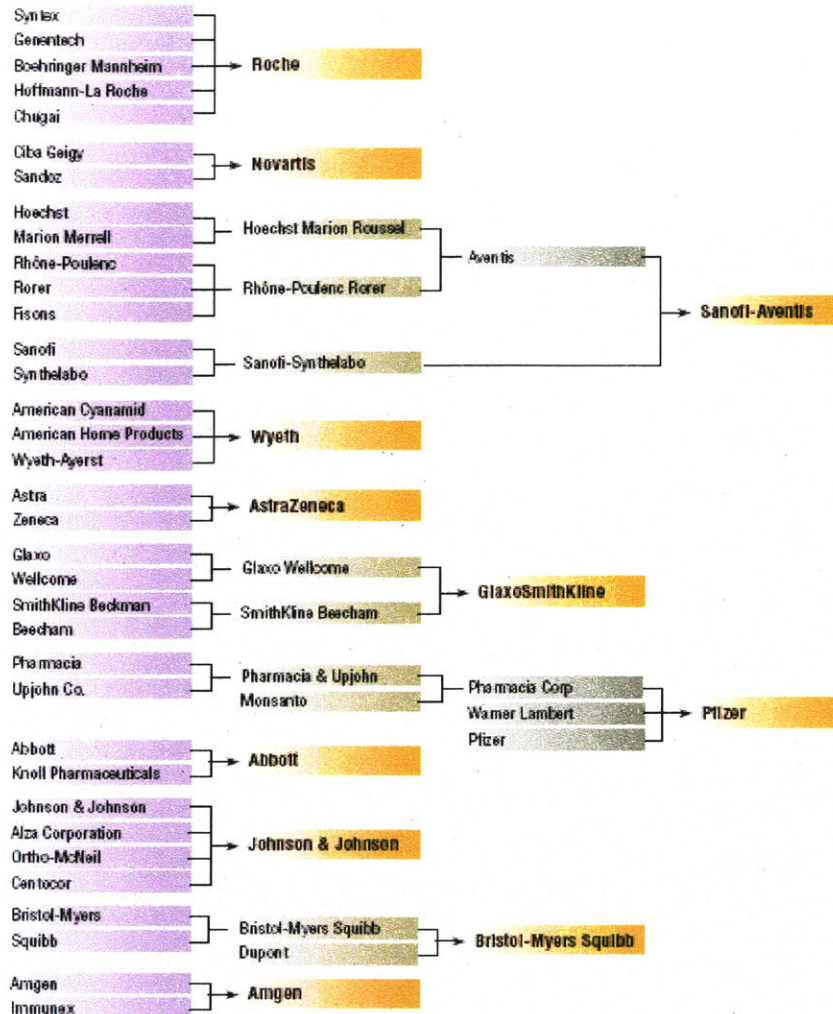
Figure 4: Prescription drug spending increases



Source: World Self-Medication Industry Federation, Tufts Center for the Study of Drug Development

Figure 5: Rx-to-OTC Switches in the United States and Europe

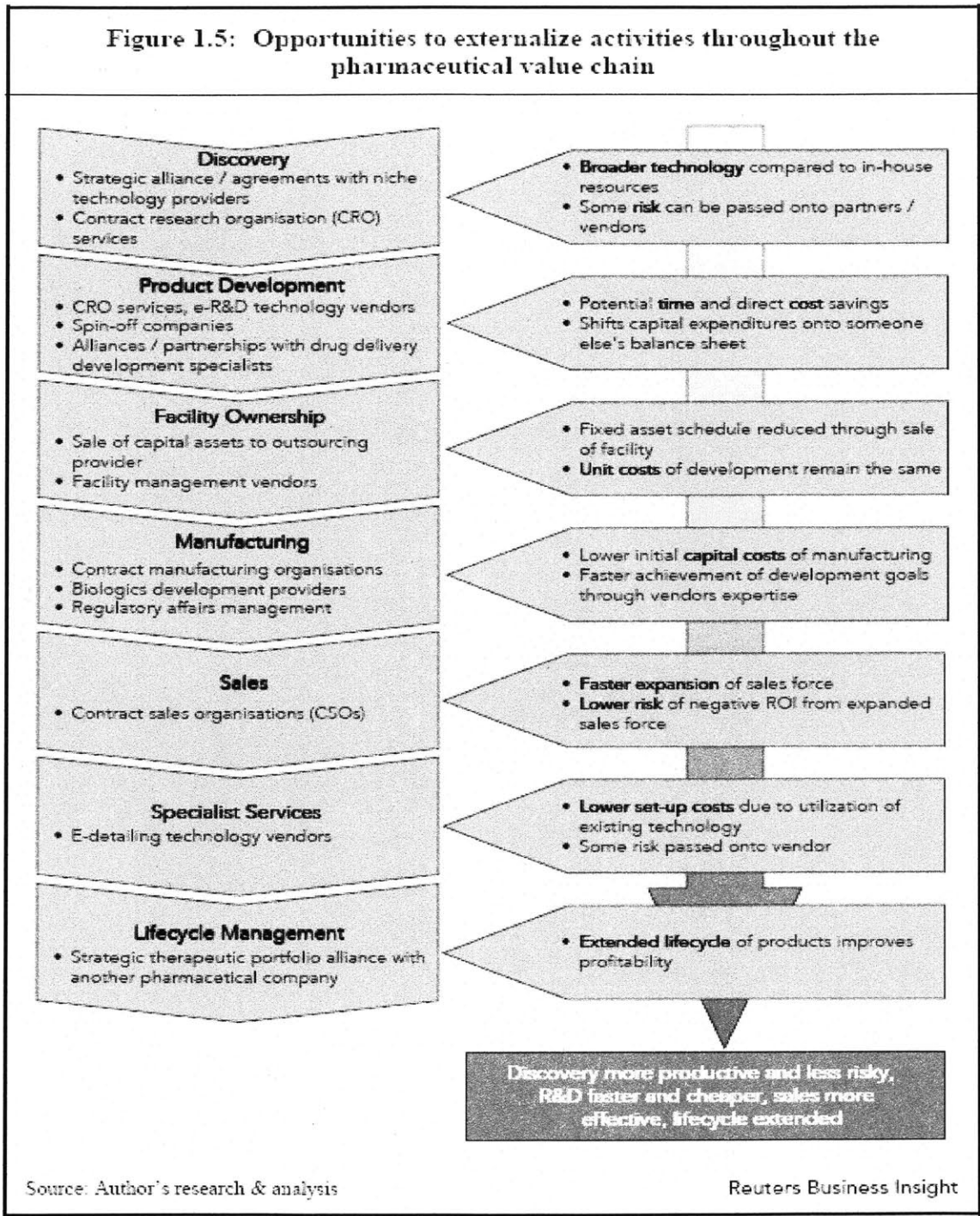




Source: IBM Business Consulting Services.

Figure 6: Numerous mergers and acquisitions have reshaped Pharma over the past 20 years.

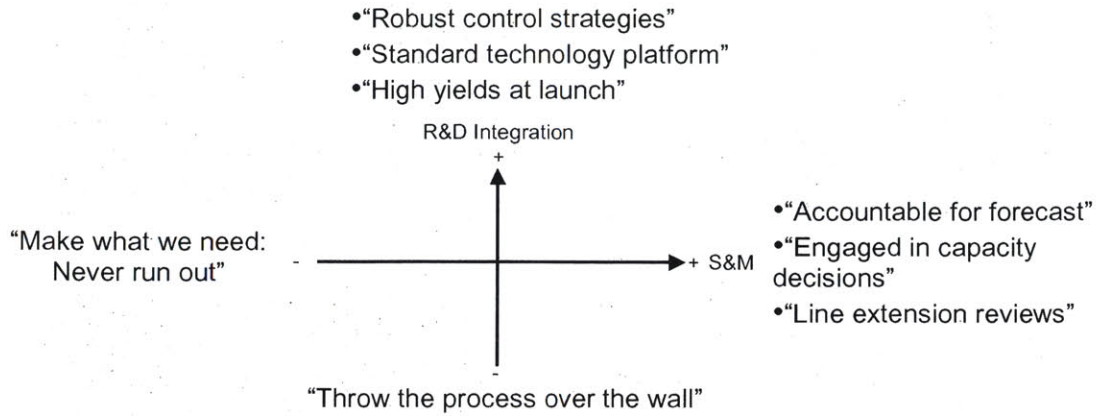
# Outsourcing Opportunities Available to the Pharmaceutical Industry



Source: Birch, S. (2002), "Pharmaceutical R&D Outsourcing strategies: An analysis of market drivers and resistors to 2010," Reuters Business Insight Report.

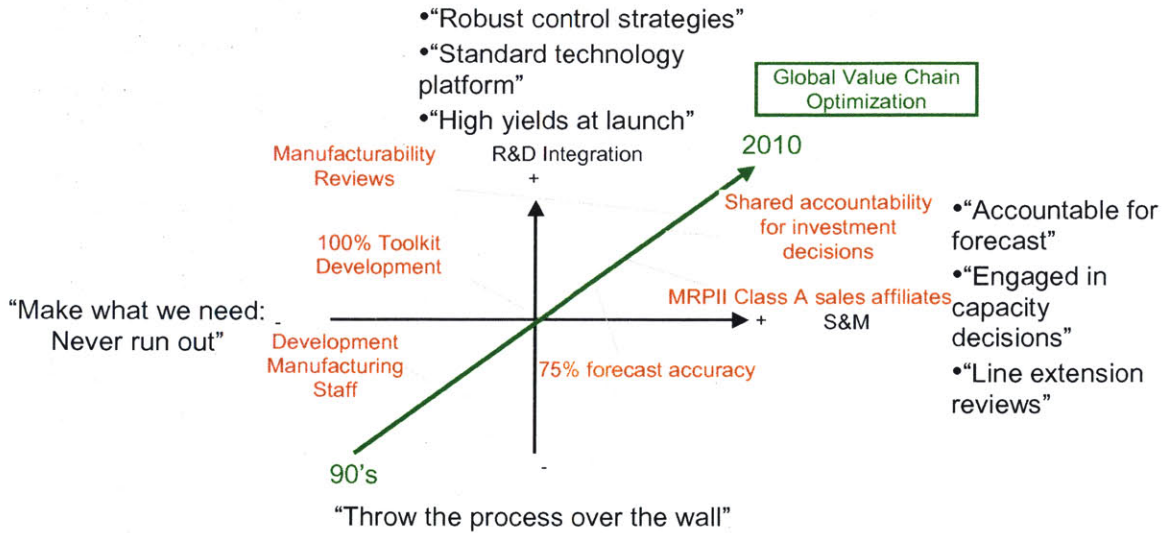
Figure 7: Opportunities

## Appendix 2



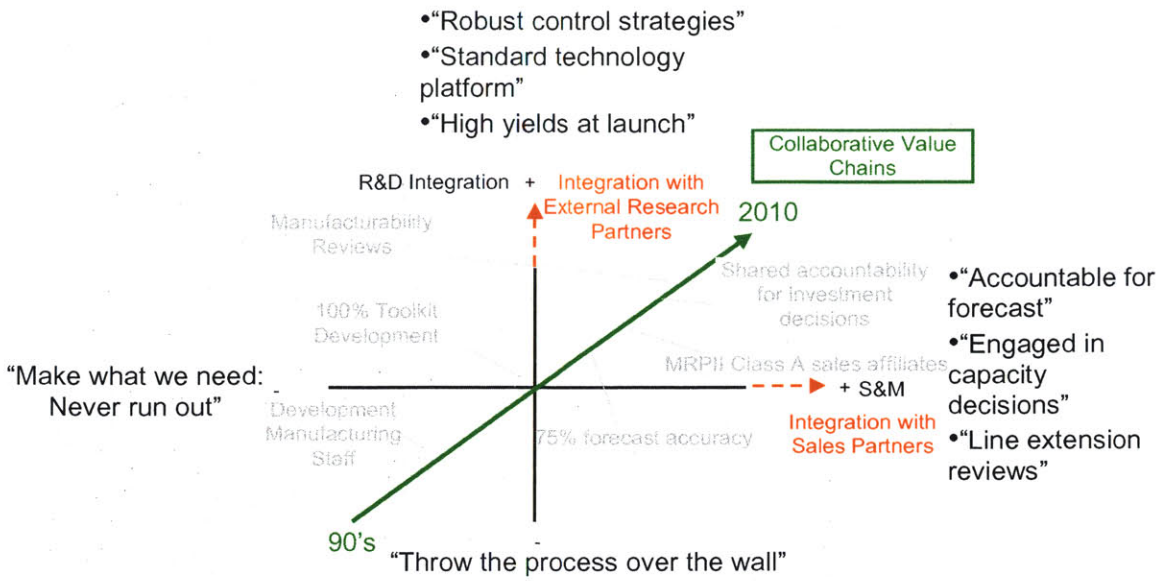
Source: Eli Lilly Company Presentation

Figure 1: S&D and S&M Integration



Source: Eli Lilly Company Presentation

Figure 2: Lilly's journey towards integration



Source: Eli Lilly Company Presentation

Figure 3: The Virtual Firm

## Appendix 3

### Chain of Care:

- ☞ Drug discovery support
- ☞ Drug development
- ☞ Clinical trial manufacturing
- ☞ Drug delivery technologies
- ☞ Dosage form manufacturing
- ☞ Package design and label printing
- ☞ Unit dose to bulk packaging
- ☞ Product launch and logistics services
- ☞ Contract sales services
- ☞ Medical education and marketing
- ☞ Repackaging
- ☞ Hospital pharmacy consulting
- ☞ Hospital pharmacy management
- ☞ Medication automation
- ☞ Automated supply dispensing
- ☞ Pharmaceutical distribution
- ☞ Clinical information management
- ☞ Pharmacy resources
- ☞ Nuclear pharmacy services
- ☞ Hospital supply distribution

Source: Cardinal Health Website, <http://www.cardinal.com/aboutus/who/index.asp> accessed on 5/5/05.

Figure 1: The Chain of Care

### Cardinal Health Strategic Drivers:

Growth: Growth fuels opportunity. We invest in our businesses so that we can deliver value to customers and shareholders.

### Key Elements:

- ☞ New Products and Services
- ☞ New Markets
- ☞ Internal Investments
- ☞ Acquisitions
- ☞ Market Share Gains
- ☞ Proprietary Offerings
- ☞ Market Leadership

Customer Focus: As individuals and as a company, our most important work relationships are the ones we forge with customers. We succeed only when our customers succeed; we put them first in the decisions we make about our business.

Key Elements:

- ☞ Innovative Solutions
- ☞ Customer Satisfaction
- ☞ Partnering
- ☞ Quality Products and Services
- ☞ Retention

Operational Excellence: We provide highest quality products and services to customers at the right time and place. We will continually improve our performance by choosing higher standards in everything we do.

Key Elements:

- ☞ Quality
- ☞ Low Cost
- ☞ Productivity/Efficiency
- ☞ Performance Management
- ☞ Regulatory Compliance
- ☞ Optimization

Source: Cardinal Health website <http://www.cardinal.com/aboutus/what/strategic/index.asp> accessed on 5/5/2004.

Figure 2: Strategic Drivers