What is the Value of Logistics for a Large Pharmaceutical Firm?

By

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Master of Business Administration, Eller College of Management
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Submitted to the Engineering Systems Division in Partial Fulfillment of the Requirements for the Degree of

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Abstract

Understanding business needs arising out of both, external and internal environments, is an essential first step in determining the value of logistics in a large pharmaceutical firm. In this research, we have used a variety of conceptual models and frameworks to explore and understand the pharmaceutical business environment and its present & future business needs. Specifically, two questions anchored the research: What will be the impact of drug technologies on logistics activities? And, should logistics activities be outsourced?

Drug technology contributes significantly to a pharmaceutical firm's revenue, but marketing also play an important role in a drug's success by influencing doctors' decisions in favor of the firm's drugs. Since it is difficult to ascertain the true value of a pharmaceutical drug, perception of service plays a critical role in conveying the positive attributes of the drugs to the potential consumers. In this context, this thesis investigates if logistics & supply chain strategy should be aligned with marketing and drug technology strategies to maximize pharmaceutical firm's competitive advantage. To this end, we investigated the impact of dominant drug technologies on the logistics function in the pharmaceutical industry as technology drives revenue growth in the industry.

It was found that business & competitive needs lead firms to develop new drugs using different types of innovative drug technologies. Indeed, the requirements of different drug technologies are different and impact business decisions related to procurement, inventory, transportation, and facility network design in different ways. Therefore, by ignoring the impact of chosen technology on supply chain design, a firm will find itself in a difficult position. Thus, we strongly believe that supply chains play an important role in extracting the maximum value out of its huge investment in drug development and marketing.

Therefore, outsourcing of logistics activities should be done only after analyzing how different drug technology categories will affect operational metric requirements of logistics activities and if logistics activities can protect the economic profits.

Thesis Supervisor: Mahender Singh
Title: Research Associate, MIT Center for Transportation and Logistics

Acknowledgement

It has been a great learning experience for me in knowing how a firm's technology can both influence and play an important consideration in its supply chain designs. By understanding its external business environment and the present & future business trends in drug technology, a firm can achieve a significant competitive advantage by leveraging its supply chain design as an important component of business strategy. All this learning would not have happened without the contribution of following people:

I would like to thank John Mancuso, Vice President Global Logistics Pfizer Corporation, and Robert McMahon, Director Logistics Strategy Pfizer Corporation, in sharing with me their viewpoint on Pfizer logistics' strategic goals and objectives. I would also like to thank Tom Elliott, Director/Site Leader Pfizer's Parsippany Logistics Center and his staff in giving me a tour of the facility and presenting their facility's present goals & objectives to me. Their critical inputs provided me with the understanding of logistics issues and challenges that the department faces in a large pharmaceutical firm.

I would like to thank my wife Dr. Rishita Tiwari who supported me in this endeavor.

Finally, I would like to acknowledge Dr. Mahender Singh for guiding me in right direction for success.

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1 Introduction

The pharmaceutical industry has witnessed a flurry of mergers and acquisitions over the years. For instance, in 1986, there were 121 strategic alliances in the industry alone, and the number increased to 400 by 1993. By 2001, there were 425 alliances between pharmaceutical firms in the first six months of the year, and an additional 383 alliances with biotechnology firms.

The current business model in the large pharmaceutical companies is built around the successful development and marketing of blockbuster[1] drugs. At Pfizer, for example blockbusters accounted for 80% of its current pharmaceutical sales. Blockbuster drugs such as Celebrex and Vioxx entered a huge, well-developed market of perennially unsatisfied but motivated patients with a non-life-threatening disease and offered significant advantages over older products leading to astronomical sales. Breakthrough products reap excellent profits for the pharmaceutical firms because these drugs tend to significantly reduce hospital stays and are highly desired in the market place for reduced patient costs.

However, the blockbuster model is not immune to problems as it is becoming increasingly difficult for companies to come up with innovative drugs on a regular basis for various reasons. Large pharmaceutical companies are trying different strategies to continually develop blockbusters but recent data is not very encouraging. These days, blockbusters are being increasingly procured through mergers and acquisitions.

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[1] Blockbusters are classified as drugs with greater than $1 billion annual revenue.

Furthermore, the pharmaceutical industry is in a state of flux with respect to which technology will drive the industry in the future.

1.1 Two Different Pharmaceutical Technologies

The products in the pharmaceutical industry can be segmented based on two fundamentally different technologies, namely chemically-synthesized compounds or small molecules and biologics or large molecules. It is important to understand the difference between these two technologies as they affect the underlying nature of the drug, which in turn has significant supply chain implications. The distinction between these two technologies is explained in some detail in the next few paragraphs.

In 1872, Paul Ehrlich proposed the concept of "lock" and "key" in enabling the drug discovery process. Ceruti and Oestreich explain the concept as follows:

"The biological process can be described as a series of coordinated opening and closing reactions, in which a "key", represented by the gene or protein that plays a role in a particular disease, perfectly interacts with its "lock", the cell surface or nuclear receptor and induces a specific process. Some diseases are therefore caused by the absence or inappropriate function of a key. Others are due to the malfunction of the lock. One way in which a drug corrects this imbalance is by substituting the missing or failing key."

However, during the time of Paul Ehrlich, technology was not available for drug firms to follow this approach to find highly effective new drugs. Therefore, the drug firms relied on "random screening" of both natural and chemically-synthesized compounds against known targets. This led to a highly inefficient approach of first creating large libraries of compounds and then testing these compounds on animals before testing them on humans to investigate the therapeutic effects of these compounds.

According to Ceruti and Oestreich, 95% of the drugs currently being used have been developed using this traditional approach, which has also led to the development of most known blockbuster drugs. These drugs attack the disease via chemical interactions and usually targeted towards broader chronic markets. Only recently, science has progressed to a level where tools and techniques can be developed to address the disease on a molecular level. This development has led to the emergence of the field of biologics.

According to U.S. Food and Drug Administration, biologics or biologic therapies are isolated from a variety of natural sources – human, animal, or microorganism – and may be produced by biotechnology methods and other cutting-edge technologies. Gene-based and cellular biologics, for example, often are at the forefront of biomedical research, and may be used to treat a variety of medical conditions for which no other treatments are available.

The stability issues associated with biologics place significant constraints on logistics activities in terms of managing cold chains, developing highly engineered packaging skills, and understanding the possible impact of RFID waves on drug stability. These complexities are likely to result in higher costs and challenging transportation issues. Whereas, chemically-synthesized drugs generally have stable structures and can be transported & delivered in cost-effective ways.

1.2 Current State of Logistics

Recent trends suggest that the pharmaceutical industry dynamics are changing rapidly and becoming increasingly uncertain. As a result of these changes, the role of the logistics department has also undergone tremendous transformation but unfortunately the changes are often ignored and not considered carefully. It is typical for the

pharmaceutical companies, especially the large pharmaceuticals to exert intense cost-reduction (and outsourcing pressures) on the logistics department without investigating the actual value of this function and its nuances.

In this thesis, we will highlight and discuss some of the key challenges and questions that we encountered during the course of researching the role of logistics in the large pharmaceuticals. First and foremost, we validated the fact that the logistics function in the pharmaceutical industry is highly cross-functional and not considered critical for the success of the organization. In most cases, cost optimization becomes the main objective of the logistics function and constraints imposed by cross-functional policies act as barriers to proper flow of value, product, and information.

To this end, we have identified two key questions to anchor our research:

1. What will be the role of logistics for a pharmaceutical firm in the future?
2. Which logistics related activities could be outsourced?

Using these as the context, the thesis attempts to explore and redefine the role of logistics in the pharmaceutical industry, especially the large pharmaceutical company. Note that we will use the terms "supply chain" and "logistics" interchangeably to reflect the broad scope of involved activities. Generally speaking, logistics activities are a subset of supply chain activities.

In principle, key supply chain related decisions in the pharmaceutical industry fall into following five decision categories: channel management; information technology; outsourcing; security & compliance; and supplier management as shown in Figure 1. Gaining a good understanding of these decision categories will lead to a better appreciation of the value of logistics in the pharmaceutical industry.

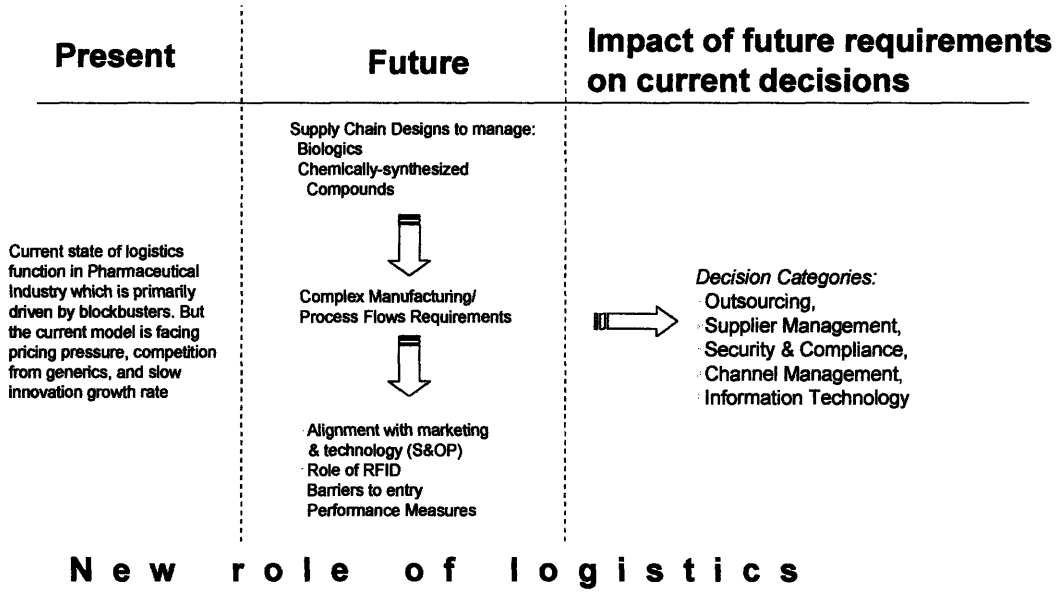

Figure 1 The Changing Face of Logistics

Lapide [27] emphasizes the importance of alignment of supply chain strategy with business strategy. In that sense, it is necessary to gain a good understanding of the business strategy in order to find the value of logistics for a large pharmaceutical firm. Academic frameworks suggest that business strategy is composed of three key components: marketing strategy, technology strategy, and operations strategy. Firms often tend to ignore operations strategy in the favor of the other two as a component of business strategy. However, recently supply chain aspect of operations strategy has gained extreme importance in providing competitive advantages to firms in different industries. The thesis explores if supply chain strategy can play an important role in protecting or enhancing economic profits of pharmaceutical firms.

The thesis recognizes the importance of the product-oriented framework that Singh [49] has leveraged to explore the state of the art of the overall pharmaceutical supply chains. The product-oriented framework is also well suited to answer the above-

mentioned questions related specifically to logistics decisions. To be sure, a firm's products and the underlying technologies embody the firm's strategy and the way that firm will choose to compete. Thus, it is natural for supply chain and logistics flows to align with the strategic product attributes. The product-oriented framework makes the decision categories quite meaningful when seen from both present and future contexts of different kinds of drug technologies.

Our research builds on the elaborate discussions on the chemically-synthesized supply chains by Singh [49] and extends the framework to the biologics supply chains. We will investigate the present and future impact of these two dominant supply chains on the overall business environment. We will use a variety of concepts & frameworks from extant literature to further enrich the discussion.

In summary, the thesis attempts to highlight the changing face of logistics in the pharmaceutical industry and identify the important drivers and parameters that the pharmaceutical companies should consider before finalizing their business strategies, organizational structures, and sourcing decisions.

1.3 Thesis Overview

Chapter 2 points out the business cases and articles that were reviewed to gather data and information on current trends in the pharmaceutical industry. Strengths, weaknesses, and limitations of various conceptual and economics frameworks are also described.

In chapter 3, we highlight threats to the economic profits of large pharmaceutical firms due to generics competition and shorter exploitation of drug patent life. Therefore, cash flow maximization of branded drugs has become the most important factor.

We explore the issue of inefficiencies that exist in the push-pull interface between primary and secondary manufacturing sites, and how pharmaceutical firms can improve their cost structures and inventory turns. It was observed that large pharmaceutical firms out perform small & mid-sized firms in managing the push-pull interface. However, amongst the large pharmaceutical firms, there is a wide disparity with respect to which firm can best manage its inventory turns. Finally, this chapter ends by specifying important operational metrics that should be considered in defining channel relationships.

Chapter 4 highlights emerging trends in biologics. As mentioned earlier, understanding product and process complexities has become increasingly important in supply chain designs due to degeneration, shorter lifespan, and complex handling requirements of biologics drugs. The industry is witnessing emergence of niche players who either have capabilities or are developing capabilities to meet these product and process complexities. Two examples belonging to Novartis' and Monsanto's biologics drugs are considered to illustrate how these firms have managed product and process complexities in supplying biologics by partnering with niche players.

The chapter also highlights an added advantage of complex logistics requirements in terms of creating entry barriers against generics competition because quality attributes for biologics are harder to define.

In chapter 5, we highlight how relevant issues related to compliance, security, RFID, and information technology impact supply chain designs.

Securing pharmaceutical supply chains is a pre-requisite for being in the business. However, pharmaceutical firms might be better off by developing a uniform platform that will lead to reduced costs and address concerns of regulatory bodies appropriately.

RFID is an emerging technology that has a lot of potential in enabling innovative strategies. At the same time, firms will have to wait to overcome certain challenges before the true potential of this technology is realized.

Chapter 6 highlights the changing industry dynamics due to increase in world's ageing population and perception of increased healthcare costs. In order to react to these changing industry dynamics, firms will have to understand to distinguish drugs based on product and process complexities.

Many issues are raised to understand pros and cons of outsourcing logistics activities acknowledging that outsourcing decisions become complicated when significant core activities have to be outsourced.

We conclude the thesis by stating that understanding business environment is an essential first step in determining the value of logistics for a large pharmaceutical firm in chapter 7. Business processes and tools are only selected when there is an understanding on how a firm would like to compete based on its perception of the business environment.

2 Literature Review

An initial understanding of the pharmaceutical industry and the challenges that the industry faces was gained by reviewing relevant Harvard business case studies written by Bradley and Weber [4], Hayes and Fagan [19], Herzlinger [20], Rangan [43], and Wells [53] and other industry-related articles written by Booth [5], and Mcgahan [31]. These cases and articles provided a good description of the industry issues and expected trends. These issues and trends will be highlighted in certain section of the thesis to augment the discussion. The data and trends mentioned in the thesis come from these articles.

Bradley and Weber [4], Hayes and Fagan [19], and Wells [53] are associated with the Harvard business school and they have similar convergence of opinions on future of the pharmaceutical industry. In their case studies, they have discussed the latest major trends driving the pharmaceutical industry as well as the relevant existing ones captured in the pharmaceutical database at Harvard University. These authors highlight the challenges faced by the top pharmaceutical firms with respect to the blockbuster business model. According to them, the blockbuster business model will not yield significant cash generation opportunities going forward as it did in the past. They attribute this to the fact that the rate of innovation is declining in the chemically-synthesized compounds.

Profitability of the blockbuster business model is further negatively impacted due to increasing competition from the generics and rapid introduction of fast-follower drugs over the years. These authors also mention the increasing presence of the biologics in the pharmaceutical space. However, they do not explore the impact of biologics on the underlying industry structure and what role they will play in increasing the industry profitability. This thesis largely accepts the trends and challenges mentioned in the case

studies by Bradley and Weber [4], Hayes and Fagan [19], and Wells [53], in the traditional blockbuster model driven by chemically-synthesized compounds.

Herzlinger [20] systematically explains the challenges and opportunities facing major groups involved in health care delivery. These major groups are: payers, hospitals, physicians and other health services personnel, medical technology suppliers, and patients. The case is presented from the point of view of New Sector Alliance, a non-profit consulting firm that is trying to make an entry in the health care sector. As a part of formulating strategy for New Sector Alliance, Herzlinger [20] provides elaborate list of endnotes and bibliography discussing the current state of the health care industry.

Mcgahan [31] has written a case study on "Merck-Medco" acquisition to express opinions on vertical integration attempts by the manufacturing firms to protect their cash flows in the pharmaceutical domain. This case study is dated but it speaks loudly about the pharmaceutical manufacturer's high level of concern vis-à-vis profitability.

The trends in the biologics technology domain are well discussed in the Harvard business case study titled "The Life Sciences Revolution: A Technical Primer" 9-602-118 written by Gary Pisano. Biologics have a potential to create immense profit for pharmaceutical firms provided technology development issues are fully resolved. Issues related to the biologics supply chain are discussed in the articles written by Anderson and Narus [1], Forcinio and Wright [15], Jarvis [22], Mullin [35], Palma [40], Vaczek [50], and Williams [55].

Since biologics is an emerging domain in the pharmaceutical industry, there is limited information available on this topic. Nevertheless, the influence of cold chains and packaging was clear in the context of logistics. To this end, we recognize the strategic

value of establishing relationships with and managing cold chain partners along with the importance of integrating and understanding packaging complexities during the product development phase.

Anderson and Narus [1] provide insights on Monsanto's biologics supply chain. This biologics supply chain shows why proprietary partnership will be required as technology becomes personalized and there are fewer patients to cure. Although the customized specialized supply chains add to the overall cost, they can offer competitive advantage by creating another barrier to entry against manufacturers of bio-similars[2]. In this manner, a pharmaceutical firm can increase the profitability lifespan of its biologic drugs beyond the limits set by patent expiration as in the case of chemically-synthesized drugs.

Issues related to chemically-synthesized supply chain are discussed in detail by Danese [9], Kulp and Randall [23], Pisano and Rossi [41], Shah [46], Singh [49], Wechsler [51], and West [54]. As it will be pointed out later, barriers to entry for the branded chemically-synthesized compounds were lowered by the regulatory bodies due to the free-rider concerns. We leverage the work done by Danese [9], Pisano and Rossi [41] and West [54] to show why pharmaceutical firms are vigorously working in gaining competitive advantage by improving availability and developing cost-optimized structures for the chemically-synthesized supply chains.

It can be argued that going forward RFID and information technology will form the backbone of the pharmaceutical industry. Following cases and articles were reviewed to understand the role of technology in this industry better: Carr [8], Forcinio [13], Giggo

[2] Bio-similar is the name given to a generic-version of biologics drug.

[16], Koroneous [25], McAfee [29], and McFarlan [32]. The issues mentioned in the Cathay Pacific case by McFarlan [32] were explored and debated upon to show why managing information technology is important. Specifically, this case study demonstrates the importance of why information technology should enable and support the firm's business strategy.

Various frameworks were used either to find the value of logistics or to find applicability of these frameworks in providing value to the firms in the pharmaceutical industry. These frameworks are given by Arrunada and Vazquez [2], Byrnes [6], Davenport [10], Field [11], Fine [12], Graves [18], Lapide [27], Lee [28], Narayanan and Raman [36], Porter [42], Rosenfield [44], and Simchi-Levi [48].

According to Byrnes [6], strategy is where the firm would like to aim and shoot. Strategy depends on how a firm views its business environment and where it sees profitability. He provides a framework of aligning supply chain drivers with business strategy by exploring the concept of extended products, the role of supply chain in account management, and choosing the right channel partners. Byrnes' framework can be leveraged to erect higher entry barriers for biologics. Davenport [10] extends a framework that describes how to align business strategy with enterprise resource planning information systems.

Lee [28] discusses how various information technology models can be used to provide a competitive advantage to firms by reducing bullwhip effects in the supply chains. Narayanan & Raman [36] provide a framework for designing supply chain control mechanisms from a systems-wide perspective and Simchi-Levi [48] shares a framework on how to design and manage supply chains. This approach takes into account

understanding trade-offs that exist in the supply chain designs and how firms can make structural changes in their supply chains to influence the trade-offs in their favor. Field [11] sheds some light on how to manage outsourcing partners in case pharmaceutical firms decide to outsource their supply chain.

Fine [12] and Rosenfield [44] provide frameworks for operations strategy where the impact of outsourcing decisions is also investigated. Rosenfield [44] also suggests a decision-based framework on evaluating important drivers that will enable proper design of operations strategy.

3 Chemically-Synthesized Compounds

The business dynamics of chemically-synthesized compounds in the pharmaceutical industry is effectively articulated in a series of Harvard business case studies written on Eli Lily in the early 1990s (Pisano & Rossi [41] and West [54]). A unique feature of large pharmaceutical companies is its heavy dependence on blockbuster, as mentioned earlier. In fact the number of blockbusters in the pipeline is an important indicator of a pharmaceutical company's financial viability in the future.

In 1992, Eli Lily was ranked 9th in the world and had a 2.5% market share; however, it had no "blockbuster" products and the firm relied on therapeutic substitutes. Eli Lily's Prozac was facing intense competition from other pharmaceuticals firms like Pfizer's Zoloft and SmithKline Beecham's Paxil. During that time, Eli Lily decided to focus on bringing new products to the market faster at lower cost.

Pisano and Rossi [41] state that due to reduced profit margin pressure, Lily's key corporate objectives were to reduce development lead time by as much as 50% and to reduce manufacturing cost by 25%. Some of the drivers, putting pressure on the margin, were: decline in pricing flexibility; slowing down of innovation rate; competition within therapeutic categories and generic substitutes. Fast follower drugs could now be designed based on blockbusters more easily. As a result of these developments, market exclusivity of a drug designed to recoup R&D investment had declined over the years.

3.1 The Role of Generics

According to the U.S. Food and Drug Administration, "A generic drug (pl. generic drugs, short: generics) is identical, or bioequivalent to a brand name drug in dosage form, safety,

strength, route of administration, quality, performance characteristics and intended use." Although generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price as the company manufacturing the generics is not investing significant resources in R&D and marketing.

More importantly, the generics trend has become increasingly more dominant over the years. And in addition, Hatch-Waxman Act, which is also referred to as the Drug Price Competition and Patent Term Restoration Act of 1984, encourages the promotion of generics in order to keep the drug prices under control.

Blockbusters now have to be discounted by up to 34% to attract market share when they approach their patent expiry. Furthermore, demand tapers off in about the twelfth year instead of full patent life because of the availability of generic and newer, patented substitutes. As a result, maximization of cash flow is gaining importance as the time to exploit new drugs commercially is becoming shorter. There is an excellent understanding in the industry that "Time-To-Market", "Availability", and "Quality" metrics are the most important competitive and performance improvement measures. In various sections of the thesis, performance measures will be highlighted to show their relative importance during the business & product lifecycle.

The generics market has more than doubled in size since 2001. In fact, prescription drug expenditure rate slowed down in 2003 due to an increased use of less expensive generic drugs, relatively lean new drug pipelines, and a slower growth of disposable income. According to Herzlinger [20], "In 2003, generic drugs accounted for 54% of prescriptions filled, but a mere 9% of dollars spent on prescription drugs. Standard & Poor's estimated a 20% growth rate for the generic drug market in 2005,

stimulated by the loss of patent protection of many branded drugs." The extent of the generics threat can be estimated by considering the case of the cardiovascular drugs. It is expected that all major cardiovascular drug classes will have intense generic competition by 2009 and that $82 billion worth of global blockbusters will have patent expiration by 2007 (PriceWaterHouseCoopers[3]).

In summary, generics competition has significantly changed the industry structure and pharmaceutical firms must take this fact into account when designing chemically-synthesized compound supply chains.

3.2 Logistics Flows

As the business model of highly profitable chemically-synthesized compounds employed by the large pharmaceutical companies shifts to the low-cost model in line with the drug's transition to its generic phase, logistics activities will have to become leaner and flexible to ward off profit pressures from follow-on superior drugs and generics. Note that the manufacturers of the generics drugs will naturally be cost focused and logistics will play an integral role in their success. All pharmaceutical firms will have to shorten the lead times and make the chemically-synthesized supply chains more responsive and flexible to meet the demand in the most cost-effective way. Furthermore, these improvements must be made without having significant impact on the throughput using proper design & placement of inventory buffers.

According to Shah [46], the inventory performance metrics of the pharmaceutical industry paint a very depressing picture:

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[3] Generic competition (http://www.pwc.com/extweb/industry.nsf/docid/004B5431685B1EEC852570A8007B5345)

- the stock levels in the whole chain ("pipeline stocks") typically amount to 30-90% of annual demand in quantity;
- finished good stocks range from anywhere from 4-24 weeks worth of demand;
- stock turns (defined as annual sales/average stock) are typically between 1 and 8. Table1 shows the stock turns belonging to various large pharmaceutical firms. As shown in the Table 1, large pharmaceutical firms have been able to improve their stock turns beyond 8;
- supply chain cycle times (defined as elapsed time between material entering as raw material and leaving as product) are often between 1K and 8K hours;
- the value-added time (time when something happens to material as a percentage of chain cycle time) is of order 0.3-5%;
- material efficiencies (the amounts of product produced per unit amount of total materials used) are 1-10%;

At the same time, these problems could be attributed to the unique challenges faced by the pharmaceutical industry such as, uncertainty in demands for existing drugs (marketing mix); uncertainty in the pipeline of new drugs; process development; capacity planning; network design; plant design; and long lead times (100-300 days are common for the overall supply chain time.)

Pfizer	Bristol Myers	Novartis AG	Glaxosmithkline	Merck Co Inc
7.92	8.62	8.17	9.94	12.79

Table 1 2006 Inventory Turns Ratios

3.3 Manufacturing Process

The manufacturing process in a large pharmaceutical firm can be divided into two main categories: primary and secondary. Primary or bulk drug manufacturing category is associated with the upstream task of producing active ingredient (AI) that uses batch equipments, has long task processing time and high production volumes, long downtimes between product changeovers, excessive inventory, and numerous quality checks. Primary manufacturing activities are heavily focused on asset utilization and produce up to a year's worth of active ingredient in one production run. Of late, primary manufacturing sites are increasingly owned and operated by contract manufacturers.

Secondary manufacturing or fill and finish operations sites on the other hand are designed to manufacture the end product in the SKU format. They tend to serve the local and regional markets. The end product is dispatched every one or two weeks by ship or by air for more frequent deliveries from the plant. A main consideration for the secondary manufacturing site location is the exploitation of tax breaks and transfer pricing opportunities. Driven by the short term and immediate gains, plant location decisions are driven by tax implications, which take precedence over logistics issues. These decisions are driven purely by financial considerations but result in potentially complicated supply chains. Trade barriers along with issues arising out of different filling and finishing specifications based on market present significant obstacles that make the manufacturing and logistics function inefficient.

In many ways, the inefficiencies in the pharmaceutical supply chains are the result of a poor interface between the primary and secondary manufacturing sites. The emergence of new technology is helping us address this problem to certain extent as

shown in Figure 2. For example, Bristol-Myers Squibb is using software from LogicTools[4] and Factory Physics Inc[5] to explore how to better manage the push-pull boundary and reduce the overall safety stock in the system. Pfizer has also relied on Tefen[6] to bring operational excellence in its processes.

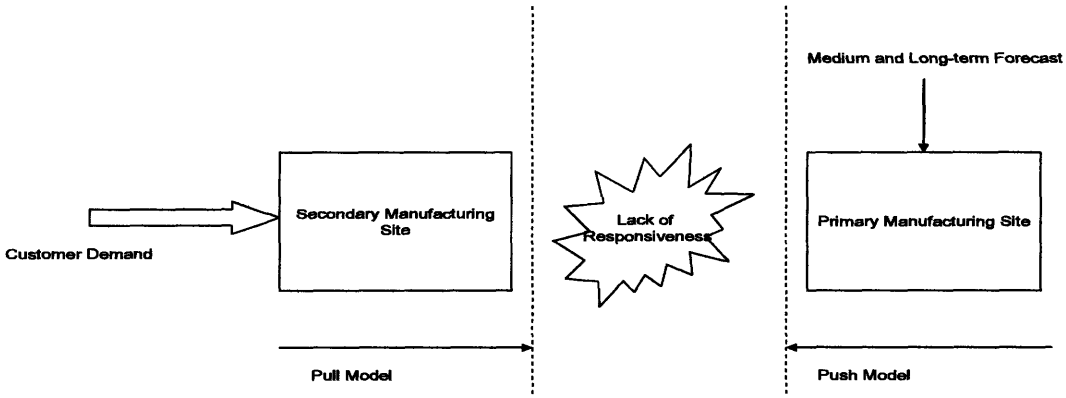

Figure 2 Inefficiencies Associated with Chemically-Synthesized Compounds

Interestingly, due to the unique nature of the primary and secondary manufacturing activities, chemically-synthesized supply chains are well suited for the application of modern planning concepts. For example, the idea of manufacturing postponement concept to reduce inventory and costs while maintaining a high level of product availability can be employed quite effectively in this situation. Since a majority of the end consumer demand is either local or regional, secondary manufacturing phase can be managed as a demand driven process, which pulls required supply from the

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[4] LogicTools, a Division of ILOG, is a strategic supply chain planning company

[5] Factory Physics Inc, is a management consulting company that provides a scientific framework, software, and training to optimize performance of manufacturing supply chains

[6] Tefen, a management consulting company that designs and implements solutions which enhance operational performance throughout an organization

primary manufacturing sites using various pull-based strategies. The primary manufacturing sites will operate in the traditional manner using push-manufacturing strategies.

3.4 Vendor Managed Inventory

Now, let us take a closer look at the vendor managed inventory (VMI) technique currently being used for managing secondary manufacturing supply chains in the pharmaceutical industry. VMI is a family of business models in which the buyer of a product provides certain information to a supplier of that product and the supplier takes full responsibility for maintaining an agreed inventory of the material, usually at the buyer's consumption location (typically a store).

Glaxo Smith Kline (GSK) was using an EDI system to exchange replenishment information with its partners in the early 90s. Despite having the EDI system, GSK faced the limitations of not knowing the true levels of inventory in its supply network. Furthermore, GSK lacked flexibility in responding to changing customer needs. The limitations and frustrations of the system led GSK to implement VMI solution under the project called Global Supply Chain in 1995.

According to Danese [9], GSK's VMI implementation extended both upstream and downstream in the supply network allowing co-ordination of the material and information flows among a number of different suppliers, manufacturing and distribution plants ("extended VMI"). It was found during the study that information was being shared both horizontally and vertically (horizontal communication implies the sharing of information between customers and suppliers and vertical communication suggests information flow from suppliers all the way to customers.)

The sharing of information within the GSK supply network allowed each actor to understand a variety of key factors such as, level of performance among supply network members; the causes behind certain results/events; and the ability of the supply network to satisfy the end customers' requirements (e.g. by analyzing the stock out in the distribution centers.) VMI implementation at GSK provided the firm with the following benefits: minimization of bullwhip effect, reduction in inventory, improvement in service levels, and ability to promise and deliver orders more effectively.

In general, the adoption VMI allows supplier/manufacturing plants to achieve a certain level of flexibility in managing the delivery and production order priority, limit inventory investment in manufacturing plants/distribution centers and improve the customer service level, as their supplier has the ability to analyze and, in some cases, satisfy new requirements even in the frozen period. VMI also opens door for a more advanced technique called Collaborative, Planning, Forecasting and Replenishment (CPFR). Additional advantages of VMI are that the demand can be managed in a more reasonable way, frequency of stock outs can be reduced, along with greater flexibility in production planning.

According to Simchi-Levi [48], the main challenges encountered during a VMI implementation include the presence of conflicting goals among supply network members; the reluctance of firms to share confidential data/information; and the need to involve supply network members through an incentive system to avoid opportunistic behaviors.

There is an acknowledgement within Pfizer that exploring the linkages between logistics and manufacturing will improve the firm's competitive advantage. To this end,

efforts are now underway to formulate comprehensive performance metrics that will measure how well various manufacturing and supply chain processes are interacting with one another and how well these processes are aligned to the firm's overall objectives. For example, fill rate metric will be used to link the performance of logistics with manufacturing.

Additionally, Pfizer relies heavily on metrics that measure warehouse processes and labor performances. The flows within the warehouse are largely segmented using drug velocities. High velocity drugs are placed near the entrance so that they can be received or shipped quickly. Six sigma and statistical process control techniques are being used to improve and measure the process capabilities to remove waste from the system.

3.5 Channel Management

Due to intense price pressures, all players in the pharmaceutical industry, namely payers, hospitals, physicians and other health services personnel, and medical technology suppliers act in their self-interest and drive industry structure changes to maximize their profit margins. For example, as Miller [34] states, the relationship between pharmaceutical firms and wholesalers is changing. Previously, wholesalers bought drugs at a cheap price and then sold them when prices increased. This model is commonly referred to as the 'buy-and-hold' model, which encouraged inefficient supply chain practices.

But recent changes in the environment have prompted the manufacturers to initiate drastic restructuring of this model. For instance, Merck announced that it would take $700 million revenue hit in the fourth quarter of 2003 to reduce the amount of

product inventory in its downstream supply chain and moderate the fluctuations in sales currently caused by wholesaler's opportunistic buying practices.

In the new 'fee-for-service' inventory management model, wholesalers will receive fees only for providing specific services. This model eliminates the quick wind-fall gains enjoyed by the wholesalers by timing the opportunistic purchase and sale of drugs. Indeed, services such as handling drugs that require maintenance of a cold chain or controlled substances requiring extra security will attract a premium and constitute a major source of income for the wholesaler going forward. Singh [49] has also investigated the impact of other mechanisms such as Inventory Management Agreements (IMAs) on the future of manufacturer and wholesaler relationships.

Availability, however, is the ultimate concern for a pharmaceutical company. Herzlinger [20] points out that pharmaceutical firms stand to loose up to $800,000 a day in lost sales for a niche medication and as much as $5.4 million per day for a blockbuster. Firms can recoup some of the revenue lost once a drug hits the market but can put millions of dollars at risk if a competitor catches up or gains competitive advantage with an earlier launch. Thus, availability is a major challenge in the early and middle phases of the branded drug life cycle. Therefore, wholesalers can benefit monetarily by providing extremely high availability services to these drugs.

Of late, maintaining custody and pedigree (referred to as e-pedigree) of a drug has gained significant importance in terms of securing and managing integrity of the pharmaceutical supply chains. Although patients and the government are negatively affected by the introduction of potentially dangerous and fake drugs into the supply chain, most of the financial burden falls on the manufacturers in terms of recalls and tarnished

brand images. Being a key player in managing the movement of drugs, the wholesalers are expected to play an important role in securing supply chains to fulfill this stringent requirement.

In addition to all the changes and challenges mentioned above, the impact of mail service pharmacies on channel relationships needs to be further investigated. Generally, this channel is suited for drug re-fills but lower cost of drugs in this channel might also lead to higher patient preference even for other drug segments. In many ways, mail service pharmacies are well suited for generics businesses. The shifting focus of channel relationships during various life cycle phases of chemically-synthesized compounds is shown in the Figure 3.

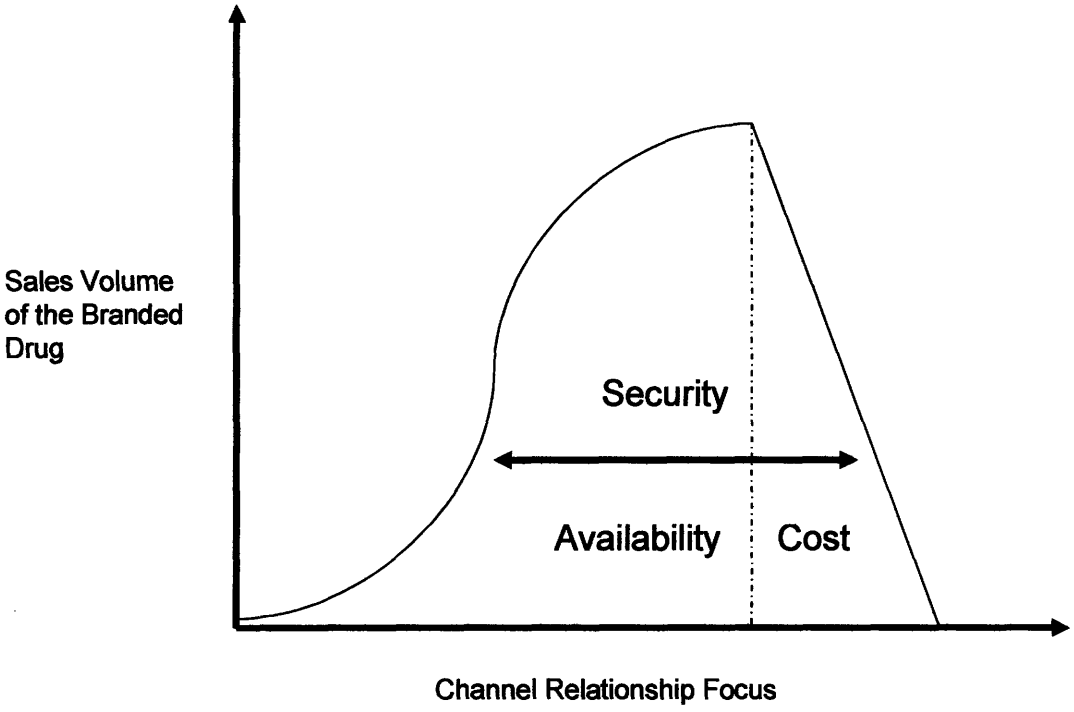

Figure 3 The Logistics Performance Measures Associated with the Drug Lifecycle

4 Biologics

There has been a lot of skepticism regarding the end of the blockbuster era in the literature and press. Various authors cite that for industry leaders to maintain historical growth rates, they would have to introduce between one and three blockbusters each year. At the same time, they talk about the emergence of biotechnology as a new field, which can serve therapeutic categories such as cancer and central nervous system disorders in fundamentally different manner, opening up new market opportunities in the bargain.

4.1 Biologics Market Trends

Currently, biologics have a smaller share of the market vis-à-vis chemically-synthesized drug category. The biologics revolution is still in its infancy and early stages of the learning curve. For now the drugs are targeting expensive and niche therapeutic markets. Wells [53] states, "By 2005, there were 1,444 biotechnology firms in the U.S., 330 of which were publicly held. Revenues increased from $8 billion in 1992 to $46 billion in 2004, and more than 320 drugs and vaccines had been developed. The industry employed 187,500 people at the end of 2004." Clearly, the sector is growing rapidly and accounts for about 27% of the global drug development pipeline.

Jarvis [22] discusses the steady expansion of Pfizer in the biopharmaceuticals space in recent years. Pfizer expects its marketed biologic products, which are predominantly recombinant protein-based drugs, to generate $1.5 billion in revenues this year, and the firm believes it can triple this figure by 2010. "We will continue to invest heavily both internally and externally and look at potential acquisitions to build on the

strong foundation that we have created," says Martin Mackay, Pfizer's senior vice president for worldwide research and technologies.

Pfizer differentiates its supply chain based on high & low velocity drugs. At the Pfizer's Parsippany logistics center New Jersey, there is a low-velocity refrigerated drug that has a potential to become a high-velocity drug in the future. It was stated that fewer resources have been currently assigned to the drug; however, in future the drug may require unique process flows and warehouse engineering skills as its velocity increases. Therefore, traditional pharmaceutical firms like Pfizer will also have to re-orient their supply chains to meet the logistics needs of biologics drugs.

There are no specific guidelines from the FDA for follow-on biologic drugs (bio-generics or bio-similars) entering the market. Being different from the chemically-synthesized drug, the quality standards for biologics cannot be established easily for follow-on drugs. This is one reason why biologics are harder to copy. Also, it has been anticipated that follow-on biologics drugs can be priced only up to 25% below the innovator's price due to high production costs and the complex processes required manufacturing the drugs.

Recently, Sandoz's Omnitrope and Biopartners' Valtropin became the first bio-similar. Sandoz's Omnitrope was developed using Pfizer's Genotropin as the reference medicine. It is interesting to note that before the US FDA approved Sandoz's Omnitrope, Genentech, Pfizer, and the Biotechnology Industrial Organization submitted citizen petitions to the FDA regarding the need for full-blown clinical trials to maintain the safety and efficacy of these drugs. The complexity of these drugs was stated as a reason.

Indeed, the biotechnology industry and large pharmaceutical firms are interested in protecting their profit margins by creating as many new barriers to entry for bio-similar firms as possible. At the same time, it should be noted that the pressure to introduce laws for reducing entry barrier for bio-similars is also quite high given the back breaking cost of healthcare in the United States.

4.2 Biologics Product Characteristics and its Unique Requirements

Needless to say, as the biologics sector matures, it will produce better quality drugs that are less hazardous and toxic to humans, have significantly lower side effects, and have faster recovery times. How it is going to happen needs to be seen as biologic product technology is inherently complex, degenerates quickly, and has a shorter life span. One of the many implications of these nuances is resulting complex handling requirements, which have significant affect on the biologics supply chain design.

To understand the complexities associated with biologics better, Stamatellos [45] illustrated a supply chain management example in the establishment of a global distribution process for a bio-engineered 5-day shelf life product. Novartis Pharma AG had partnered with a local startup in Cambridge, Massachusetts to supply skin grafts to patients around the world. Some of the challenges were how to forecast the demand for the organ, what kind of special packaging is needed to nourish the organ that could live only for five days from the time it was manufactured, and how to ship the organ without delaying it and making sure that the organ is with the physician when needed.

To meet these challenges, the logistics department partnered with air delivery & freight services firms such as FedEx Corporation. Novartis developed a special packaging technology to provide the continuous nourishment to the organ as it was being

transported and utilized the tracking capabilities of FedEx to know the exact location of the organ at any given time. The emphasis was on ensuring that precautions and instructions were followed reliably to ensure that organ reached the end customer in the promised state.

Furthermore, Novartis logistics team worked seamlessly with the sales force that was trained to work closely with the physicians ordering the organs. The redesigned supply chain that leveraged the close interaction between the sales personnel and the physicians enjoyed 99.97% forecast accuracy for the organs.

In the future, it is likely that biologics will lead to the development of 'designer drugs' that can address unique needs of an individual based on his or her gene profile or for a group belonging to a certain demographic profile living in different geographic locations or countries. Consequently, it will be a challenge as well as an opportunity for pharmaceutical firms to service these discrete and smaller sets of patients but it will require an increasingly sophisticated supply chain function to meet the new challenges.

Monsanto's Animal Agriculture Business (MAAB) developed an innovative modular channel to highlight the importance of selecting channel partners with appropriate capabilities. In 1993, MAAB came up with the first rBGH drug called "POSILAC" that increased milk production of dairy cows. MAAB developed the channel for "POSILAC" using a network of third-party information technology, logistics, and cash management suppliers.

The customers of rBGH were 130,000 active dairy farmers spread across the United States. MAAB hired Marketing Technologies International Inc. (MTI) to design and develop AGLIFE database on these farmers as well as hired Geile-Rexford, an

advertising agency to create and mail a launch kit, featuring a video and collateral material, to the prospective farmers. FedEx logistics services (FLS) built an integrated logistics system to support this project and flew the POSILAC in bulk containers to its Memphis hub and stored it in the refrigerated warehouse. With the help of the new system, the FLS employees could assemble an order and ship it to the dairy barns belonging to the farmers in a very short amount of time.

To complete the cycle, Browning Ferris Industries (BFI) gathered, and recycled used syringes while Moore Business Forms issued monthly statements to dairy farmers concerning their POSILAC usage. Furthermore, to promote sales, Bank of America extended financing to help farmers buy the new drugs. As a result, by 2001, POSILAC was the largest-selling dairy animal pharmaceutical in the United States.

The above two cases highlight the complexities involved in both the product and process technologies in developing and marketing biologics. The complexities might lead to the emergence of niche logistics players who will provide unique services to biologics manufacturers enabling their supply chains. Furthermore, consider a drug that is priced at $30,000 per annual treatment and has only 16,667 customers, the annual revenue for the drug is approximately $500 million dollars, but the small number of customers will most likely be located all around the world. In order for the drug to reach its potential customers in the time-sensitive period, a pharmaceutical firm will have to rely on the niche logistics players or build sophisticated supply chain capabilities.

Obviously, targeted potent drug molecules in the future will require much smaller dosage. As a result, their production volumes will be relatively low compared to the current drugs; however, more manufacturing capacity per output unit will be needed due

to the manufacturing difficulties associated with these new drugs. It is anticipated that in the future, it will be costly to keep finished goods inventory because these drugs are high-value added and expensive to handle. Therefore, managing inventory for biologics is expected to become more challenging year by year.

In summary, both the production cost and quality control requirements are high for biologics compared to chemically-synthesized compounds. Thus, biologics cannot be easily copied and it becomes essential for the innovator firms to protect both product and process intellectual properties. By doing so, pharmaceutical firms might be able to delay the entry of bio-similars.

4.2.1 Cold Chains

Biologics are highly temperature sensitive. If these drugs are not kept in the required temperature controlled storage conditions, the strength, purity, quality, and efficacy of the drugs will suffer. It is interesting to note that FDA considers temperature abuse in its definition of adulterated product. Therefore, pharmaceutical firms will have to take into account of making sure that biologics are maintained under appropriate temperature conditions even while in transit. Moving pallets of several cubic meters within the 2-8 ℃ window poses a significant challenge to the logistics function. The logistical nightmare has given rise to new breed of logistics firms that specialize in moving highly unstable products at low temperatures. Logistics managers will now have to contend with reductions in potency due to temperature excursions. Airport delays are the biggest cause for biologics damage due to temperature excursions.

According to the current trends in the biotechnology sector, the growth in temperature-sensitive products will outpace the rest of the industry with average growth

estimated at 15% per year. Nearly 70% of the biotechnology drugs approved in the last six years can be classified as temperature sensitive. In 2003, biologics accounted for approximately 10% of $400 billion of pharmaceuticals and biotech products grew at a rate twice that of small-molecule drugs between 1999 and 2003.

According to Vaczek [50], FedEx Custom Critical Inc. (Akron OH) offers its temp-assure validated ground services employing thermal-mapped vehicles equipped with NIST-traceable recording devices. The Custom Critical shipping tool kit provides online shipment monitoring with temperature updates every 30 minutes. With the Temp-Assure Validated Air service, U.S. and overseas freight is transported in temperature-controlled vehicles by FedEx airlift.

More importantly, logistics will now have to align with R&D during the early phases of drug development to understand the stability issues and how to deal with them. The cold chain will force pharmaceutical firms to view the supply chain holistically and how to manage and run it.

As a result of the criticality of the cold chain in moving biologics, pharmaceutical firms will have to be extremely careful in choosing their cold chain transport partners. Considering the product and process complexities, the relationships with the channel partners will have to be both strategic and proprietary. New information technologies are bound to play an important role in enabling these relationships.

4.2.2 Packaging

Another important aspect of protecting the stability of biologics during the duration of its shelf life is packaging. There are only a few articles written on the role of packaging in the biologics supply chain and that too during the past couple of years. This suggests that

packaging is slowly but surely gaining recognition as an important part of the design of biologics products.

Williams [55] highlights the importance of packaging in the pharmaceutical industry. According to him, the partnership between pharmaceutical firms and the packaging firms should be treated as significant for maximizing security while reducing costs.

To be sure, biologics are increasing the need and complexity of packaging technology as foreign substances emitted by packaging technology can affect the sensitivity of many biological drugs. According to federal regulation, packaging firms now have to ensure drug integrity throughout its complex supply chain.

Forcinio and Wright [15] state that managing cold chain appropriately can increase supply chain efficiency and reduce costs. RFID can play an important role here. At the time of writing, the authors state that no federal regulations define cold-chain packaging standards. Sensitech, Beverly, MA (www.sensitech.com) is working on technologies related to cold chains using RFID technology.

Specifically, Sensitech is aiming to develop a solution that will record temperature and humidity at specified intervals and wirelessly download the data to a web-accessible database. As a result, actions can be taken proactively if temperature breach is noticed; thereby addressing the root-cause and preventing further damage to the drug. Sensitech's marketing director, Henry Ames illustrated this problem by sharing the case where "an entire shipment of biologics was frozen, causing an $8-million loss." Thus, RF-generated information can help logistics managers to save on coolant and

attendant dead-weight shipping costs. These costs savings are attributed to matching packaging capabilities to the shipment conditions.

4.3 Channel Management

Cantow and Strauss [7] state that Boston Scientific prefers to ship its medical instruments directly from its distribution center to the end-users or doctors. The reason behind this practice is that the product innovativeness requires a specialized sales force that has to communicate and work very closely with the doctors. Customer contact is essential for making a sale and maintaining high market share in the medical device industry. Thus, a lot of customer contact is lost if the product flows through distribution centers and warehouses that are not owned by Boston Scientific.

One of the key learning of our research so far is the heavy influence of product technology on the design of logistics flows in the pharmaceutical industry. Extending this argument into the future, we can conclude that the future supply chains will be very different from today mainly on account of the highly complex products in the future.

As a result, firms will have to be careful in terms of which activities they can outsource. It can be argued that strategic planning activities will have to be retained within the firms. The industry segment is dependent on protecting its intellectual property to raise the entry barriers against the generics. Having a direct impact on the performance of the drugs, biologics supply chains will seek innovative solutions using latest technologies.

5 Additional Considerations

We now turn our attention to several other factors that are important to recognize the value of logistics for a pharmaceutical firm.

5.1 Compliance

FDA strictly enforces regulations to prevent errors as the drugs move downstream in the supply chain. According to Neway [38], FDA initiated systems-based inspections enforcement in 2002 to this end and issued many citations regarding quality, production, & laboratory systems. The reason for the citations was the manufacturing inefficiencies that affect various pharmaceutical firms.

5.1.1 Process and Analytical Technology

There is a general perception in the industry that pharmaceutical firms have relied on standalone applications that were designed with a silo mindset. Some people say that in order to counter the mindset, the FDA introduced Process Analytical Technology (PAT) initiative. According to the FDA website, PAT is a system for designing, analyzing, and controlling manufacturing of critical quality and performance attributes of raw and in-process materials and processes with the goal of ensuring final product quality.

Pharmaceutical firms will require new information systems to process large amount of data and convert it into meaningful information to satisfy PAT requirements. According to Neway [38], "The lack of timely, cost-effective data availability with connectivity to the point of use may be the single largest hurdle to compliance and operating efficiencies in pharmaceutical manufacturing today." It might be worth noting

that GlaxoSmithKline was the first firm that worked with FDA to incorporate process analytical technology initiative.

In order to comply with the FDA regulations, pharmaceutical firms will have to improve the tracking and tracing capabilities of drugs, monitor stock levels, avoid out-of-stock situations, automate reordering and inventory counting, and minimize counterfeiting. Thus, cycle time reduction goals have gained significant importance in the industry.

5.1.2 Managing Compliance

Compliance in a pharmaceutical industry is both mandatory and necessary to stay in the business.

There are perhaps two options for pharmaceutical firms to deal with compliance issues that improve quality and reduce costs concurrently. In the first option, pharmaceutical firms can modularize their compliance activities and outsource certain segments to specific partners. This type of outsourcing arrangement can help a company leverage scale advantages, and thereby lower costs of managing and maintaining compliance activities. In the second option, pharmaceutical firms will have to develop innovative processes that will enable them to reduce costs while maintaining quality in compliance activities. Both these options might be feasible; nevertheless, pharmaceutical firms will have to judiciously decide on which option fits best based on intellectual property issues and the current business environment.

5.2 Security

According to Wechsler [52], "Some counterfeit versions of Procrit (epoetin) contained non-sterile tap water that can cause blood stream infections." In 2002, counterfeiters substituted insulin for Eli Lilly's (Indianapolis, IN) injectable drug Zyprexa (olanzapine). A counterfeit version of Serono's (Rockland, MA) had no active ingredient at all. Pfizer (New York, NY) recently warned pharmacists of a widespread distribution of unauthorized Lipitor (atorvastatin calcium) tablets that patients found to have a bitter taste. "FDA notes that Chinese counterfeiting of some drugs may be as high as 50%, and estimates are about 40% for fake pharmaceuticals in Argentina, Columbia, and Mexico." Some of FDA's enforcement actions resulted in following fines: TAP pharmaceuticals ($879 million settlement for violations of PDMA); Schering Plough ($500 million for failure to comply with good manufacturing practices); AstraZeneca ($355 million for healthcare fraud).

These examples illustrate the importance of securing pharmaceutical supply chains. In fact, security has become a critical requirement in the industry. However, it is not a source of competitive advantage. The pharmaceutical industry along with the FDA will benefit by collaborating and developing the framework that will enable highly secured supply chains.

Securing pharmaceutical supply chains involves actions at the item level, case level, and pallet level. There are two approaches to secure supply chains using covert and overt technologies. The covert concept hides the form of security by using security markers or taggants on drug coatings and the packaging material. Latest technology to prevent counterfeit drugs comes in the form of taggant solution. Taggants are made of

food grade materials that can be incorporated into the packaging as adhesive, coating on a label, or on the cap. Taggant code is read using a micro-imaging reader and software, which allows authentication at the pill level. Many high-tech firms have emerged in this space and are trying to develop new technologies using innovative ideas. The overt form of technology tries to secure supply chains using visible markers like holograms and color-shifting ink.

FDA uses carrot and stick policies to manage security. FDA would like to see the use of RFID in tracking the pedigree of a drug. While at the same time, FDA has decided that it is up to the industry, professional societies, and voluntary standards organizations to fill in the details of the path ahead.

In the present scenario, RFID Tags are expensive and they are currently used where the biggest value is. Nevertheless, RFID tags enable tracking the pedigree of a drug from creation to purchase much more easily than what can be achieved using the paperwork. Currently, major pharmaceutical firms are planning to ship high-risk drugs using RFID. This action will lead to securing high value cash flows.

5.3 The Role of RFID

A key emerging role of RFID is to secure pharmaceutical supply chains and to execute compliance policies. RFID microchips that contain product code are embedded into the package so that the product can be tracked along the entire supply chain. To further enhance the value of RFID, the pharmaceutical firms can borrow application ideas from other industries. For example, Kimberly Clark hopes to achieve the following using RFID: visibility up to the shelf inventory, improved forecast, and serialization of data to resolve shipping/receiving discrepancies. RFID can also enable better management of

drugs recalls, item level traceability, channel management, cost data collection, and management of charge backs and rebates.

But before deciding in favor of RFID, pharmaceutical firms will have to prove that radio frequencies don't degrade the efficacy, purity, or safety of sensitive biologics. Also, the onus falls on the pharmaceutical drug manufacturers to manage encryption of the RFID tags using private keys and avoid imposing additional resource constraint on supply chain organizations of these firms.

Additionally, the RFID technology has had some technical challenges in terms of product and process deployment. However, the ultimate evolution of the RFID technology will be in the service space. Here, RFID can be used as a source of differentiator allowing strategies that will produce new value and enable new business practices. An integrated RFID technology solution will enable synchronization of marketing, supply chain, and technology policies. Thus, firms will have the flexibility to meet varying customer needs.

5.4 The Role of Information Technology

According to McFarlan and Delacey [33], the merger of Pfizer with Pharmacia in 2003 led to the following priorities for IT: consolidation of data centers, combining of networks, and choosing of applications. Thus, ITLT group was created to support this mission. Some of the challenges that the group experienced were: the product pipeline carried the ever-present risk associated with the development of new drugs, but risks also existed for established drugs. What would happen in future when Lipitor went off patent? If revenues were to fall rapidly, as they do when drugs go off patent, what would happen to IT capabilities relying on a larger revenue base? The ITLT served as a template for

how Pfizer organized IT activities across business groups. With the addition of Pharmacia, and the resulting increase in firm size and differenced in IT processes and systems, it was not clear if the ITLT model for organizing IT would continue to be effective.

The outcomes highlight the complexity of the work that is required to develop IT strategy for a firm of Pfizer's size. McAfee and Reavis [29] state that the pharmaceutical firms' top challenges in implementing e-commerce were: difficulty connecting to partners, lack of corporate support and strategy, security authentication concerns, difficulty finding IT resources, expensive technology, and difficulty connecting to installed systems. There are also certain challenges such as disparate regulations regarding the manufacture and sales of pharmaceuticals, significant differences in the costs of pharmaceuticals, and different ways in which cultures treat ailments.

At the same time, there are signs that pharmaceutical firms are recognizing the importance of centralization of information systems. The centralized strategy reflects the importance of control & co-ordination, and cost effectiveness of the pharmaceutical operations. This is especially true for chemically-synthesized supply chains. For example, in December 1999, Novartis moved away from internally developed e-procurement system to an Ariba e-procurement system when the firm recognized the need for a global system. Novartis also revamped its ERP system to make it globally compatible. It had 60 separate ERP systems that ran SSA software to fit the various needs of CSOs and plants. There was a general consensus amongst the management team of Novartis that a single interface is needed for customers. Novartis chose SAP that would comprise seven data centers. The guiding principles for e-business strategy at Novartis were: greater focus on

implementation; importance of speed of execution; prioritization of areas where most impact can be made; respect and recognition of different market needs and resource levels; global is good, but local delivers fast results; and integrate and do not become isolated.

Following case study illustrates the importance of the role of information technology in a corporate setup and to understand the impact of IT decisions on business strategy.

5.4.1 Cathay Pacific Case Study

A. CENTRAL BUSINESS and I.S. ISSUE (S)

At the time when the case was written in 2002, the global airline industry incurred a $9 billion loss.

Some of the issues facing Yeung, the CIO of Cathay were: How should Cathay direct its IT expenditure and in what other ways could savings be achieved? What were the threats posed by "no-frills" airlines in the future compared to "long-haul" airlines? How should Cathay increase the return on investment? IBM benefited immensely from the smartsourcing alliance as it got access to Cathay's talented employee pool and was making similar deals with other Asian airlines. Thus, the smartsourcing deal that Cathay initiated certainly had limitations. What were the lessons learnt? What can be done to mitigate the shortcomings of smartsourcing? How will long term IT strategic decision impact two hundred systems delivery employees who had supported in-house legacy applications? What should Cathay do with 3,200 out-port workstations? Should Cathay outsource its entire IT operation? How should Cathay manage its vendors? How should

Cathay manage its outsourcing process? What are the threats of outsourcing? Can Cathay utilize talented pool of IT engineers from China?

B. ALTERNATIVES/OPTIONS/RECOMMENDATIONS/IMPLEMENTATION

It was essential that Cathay strengthened its strategic position in the marketplace. The "no- frills" airlines were not really a threat since it fits well for domestic short-haul point-to-point travel, however, for a long-haul international travel, brand image, track record, on-time service, safety, and quality of service provided are important parameters.

In general, information technology enables business strategy and either generates high revenue or reduce operating costs. Simply put, information technology should act as a bridge between customer expectations and services provided. The goal should be to increase desirability amongst passengers to choose Cathay, and as the passenger volume increases, Cathay will see benefits of scale in terms of reduced unitized costs. Thus, Cathay can develop cost advantage over its rivals and it can also satisfy its strategy of offering premium products while keeping costs low.

In order to support its information technology objectives, Cathay can keep its existing systems workforce to develop and maintain its customized applications. This will allow Cathay to own the proprietary technology, which will support its strategic objectives and internal activities. However, the IT team might not be able to meet corporate objectives due to lack of quality resource availability and engineering inefficiencies. Delays incurred in developing applications besides lack of innovation in the design team may lead to inferior products compared to the off-the-shelf technologies.

Other options include relinquishing some control of development activities by having relationships with firms that have superior capabilities in developing information

technology applications. These relationships can be in the form of: a transaction relationship; a co-sourcing alliance; and an enterprise partnership.

A transaction relationship works best if the firm out-sources its well-defined and repeatable activities to a vendor who can perform the activities better. This can reduce costs, yet maintaining or increasing quality. Cathay was already having a transaction relationship with IBM when it outsourced its data center. Disadvantages of a transaction relationship are that if service levels and penalties for non-performance are not well defined, Cathay will have to bear the risks of accountability and ownership of the outcome. Generally, initial momentum and excitement wanes after 3 years and the relationship often deteriorates into us vs. them mentality.

Using a co-sourcing alliance, Cathay can leverage strengths of a business process of its co-sourcing partner to achieve strategic objectives. In this model, another firm will help Cathay extend its own brand capabilities, often in ways that are not built on customer-facing processes but on "back office" and "administrative processes". Here both the co-sourcing alliance partner and Cathay will be responsible for meeting the goals and operational metrics. A co-sourcing alliance will suit Cathay if it is lacking capabilities to develop certain processes that are critical in meeting its strategic objectives. However, teamwork and collaboration between two organizations is challenging. In addition, risk is involved when the co-sourcing partner implements the same solution for a competitor and learns from the innovator's experience.

The prime motive of an enterprise partnership model is that Cathay will get cost savings and better services. The partnership will be owned jointly by Cathay and its technology-supplier. Project outcomes are certainly unknown, thus, the supplier also

bears the risks. Advantages of an enterprise partnership are: infusion of external energy and capabilities; clear indication that management is committed to transformation; upfront investment made by supplier. Cathay will bear less risk than the supplier because Cathay receives guaranteed rewards, even if the supplier has to deliver the rewards at the expense of its own profitability. Disadvantages of an enterprise partnership are: supplier becomes responsible for management and operations of the new entity; the enterprise partnership approach creates a clash of cultures; supplier's technology does not guarantee competitiveness in the open market; enterprise partnership does not perfectly align with the incentives.

6 Analysis

The framework shown in Figure 4 presents the pharmaceutical industry dynamics and identifies important drivers that are either affected or will be affected by the supply chain & logistics decision categories. A firm's decision categories directly impact the competitiveness and performance measures. Typically decisions are made based on how the firm views its short-term and long-term external and internal environments that are represented by the product & business lifecycle. Thus, by understanding the product and business lifecycle, the firm can decide on how to influence its competitiveness and performance measures by making appropriate decisions.

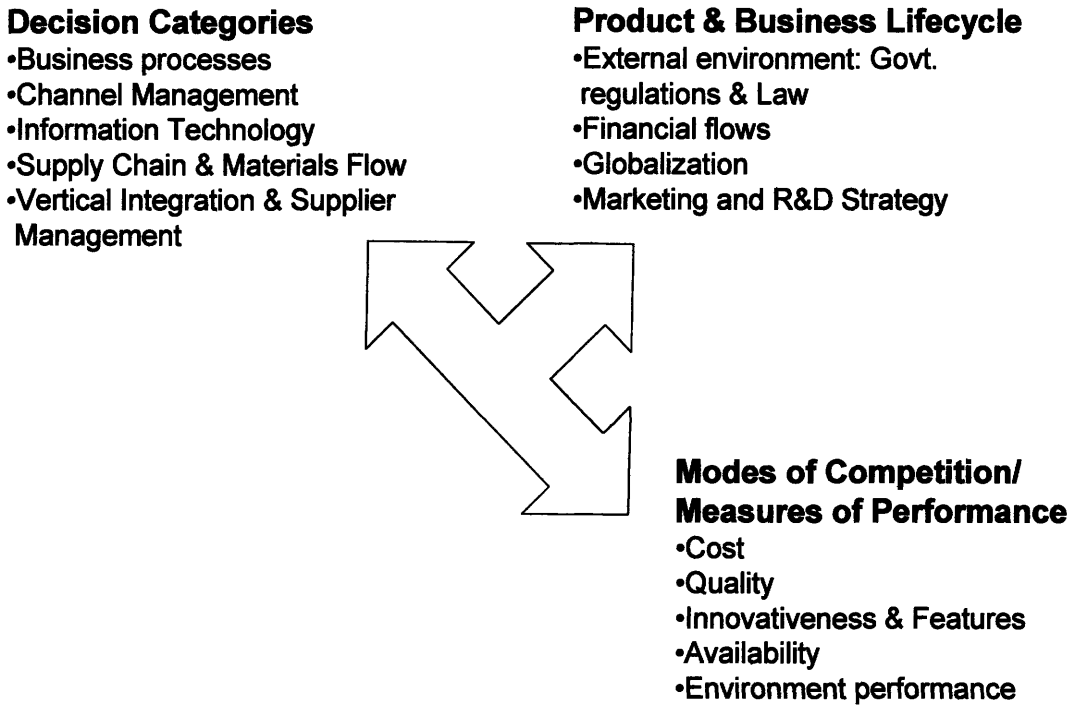

Figure 4 The Framework to Find the Value of Logistics in the Pharmaceutical Industry

In the following sections we will bring together findings from previous chapters to create scenarios that will demonstrate the value of logistics for a large pharmaceutical firm.

6.1 The Pharmaceutical Industry Dynamics & its Impact on Logistics Design

It is well documented that the dynamics of the pharmaceutical industry is changing. The competitive forces that the industry has experienced in the past and expected to be present in near and mid term future are discussed below. We also highlight some of the key dynamics that have the potential to change the industry structure in the long run.

Let us take a closer look at the causal loop diagram presented in Figure 5. From the figure it can be observed that a key determinant of the future health scenario will be the ageing of the population of the developed world. One of the critical aspects of ageing will be the likely increase in the infection rate or the disease susceptibility of the population. As a result, there will be a corresponding increase in the number of people requiring health care, which will have a spiraling effect on the overall health care cost.

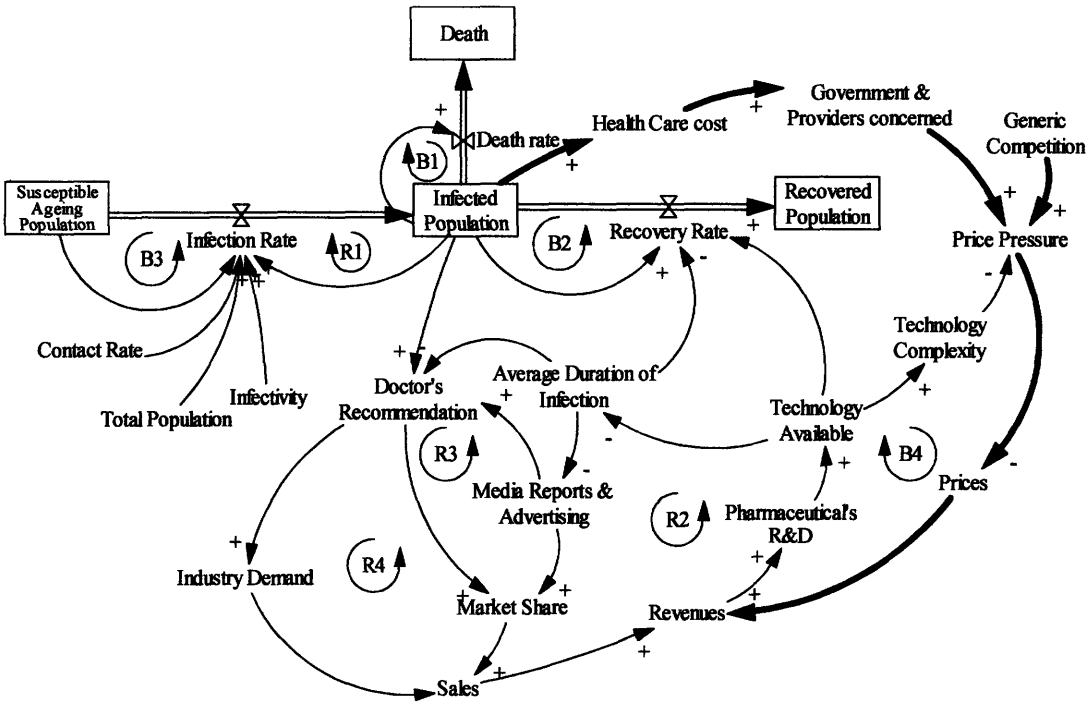

Figure 5 The Pharmaceutical Industry Dynamics

This development will have a direct financial impact on the pharmaceutical companies. On the one hand, opportunities to develop and sell more drugs will present themselves to the pharmaceutical companies, on the other hand, the Government and health care providers will face increasing pressure to take steps to lower health care costs. This problem will be exacerbated by the competitive pressure exerted by an increasing number of generics entering the market place due to the patent expiration of a large number of blockbuster drugs and slower rate of innovation especially for the chemically-synthesized compounds. Section 3.1 discussed how generics are changing the industry structure and why chemically-synthesized supply chain needs to be more responsive and flexible to the demand.

In the current business model, innovative technology is the main driver of industry growth. New innovative technology tends to cure complex diseases or improve

the quality of life in terms of faster recovery, less adverse side effects, and thereby preventing costly hospital stays. These benefits of the innovative drugs motivate doctors to prescribe them to the patients. Media reports and advertisements further fuel the popularity of these drugs. The increased revenues act as a fuel for further research and development that result in a larger number of innovative drugs by kicking in a virtuous cycle.

The growth loops (R1, R2, R3, R4) supported by R&D are being actively counteracted by the balancing loop (B4) to reduce prices. Thus, the business dynamics pose significant profit challenges for large pharmaceutical firms due to increased price-reduction pressures from the government bodies, health-care organizations, and competition from generics.

Additionally, different diseases have different footprint in terms of target population sizes. For example, some diseases affect fewer people and are labeled rare. Indeed the technology to cure rare (and often life-threatening diseases) is typically more complex requiring complex manufacturing processes. In a peculiar way, the mix of product and process complexities provides significant competitive advantages to an existing player and high barriers to entry for new firms in terms of technology, highly-skilled resources, complex processes capabilities, and high manufacturing costs. Section 4.1 explained how biologics as an emerging technology might create entry barriers and protect profit margins.

This interaction between price and population is captured in the model shown in Figure 6 where the size of the population affected has direct relationship with drug prices. According to this proposition, diseases that affect a large population base will eventually

result in cost-optimized structures. These cost-optimized structures will be based on leveraging the benefits associated with scale such as risk pooling, outsourcing etc. Sections 3.2, 3.3, and 3.4 discussed the postponement strategy that can reduce inventory and costs in the chemically-synthesized supply chains along with the improvement opportunities at the push-pull boundaries.

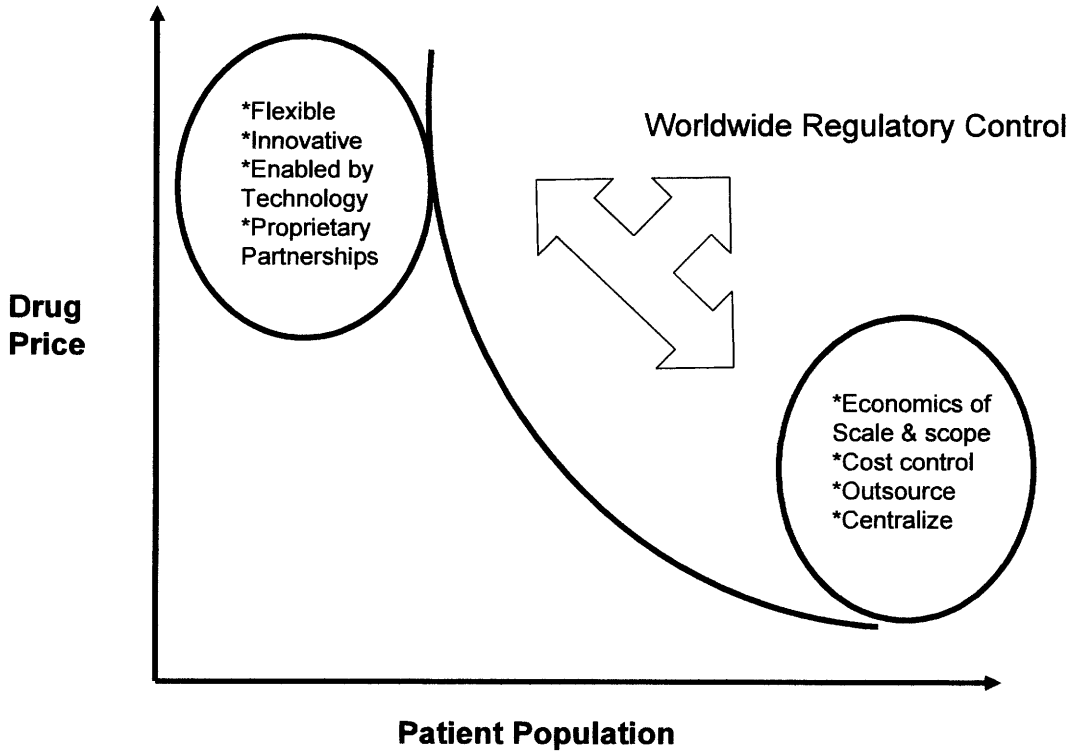

Figure 6 The Drug Prices vs. Patient Population

Whereas diseases that affect smaller patient populations will require flexibility, proprietary relationships with niche players, and the innovative use of technology resulting in higher cost. Section 4.2 presented in greater details the impact of biologics complexity and its instability leading into the discussion around cold chains and packaging. Biologics products will require expertise in understanding and managing cold

chains. Also, packaging expertise is essential in handling biologics' product and process complexities.

Let us now turn our attention to the impact of above-mentioned business dynamics and economic model on supply chain & logistics function. This analysis is captured in Figure 7. As mentioned earlier, complex technology will cost more and provide adequate barriers to entry unless the industry structure changes. The complex technology will require proprietary supply chains that should be able to move highly unstable and complex drugs in the shortest period of time to fewer patients.

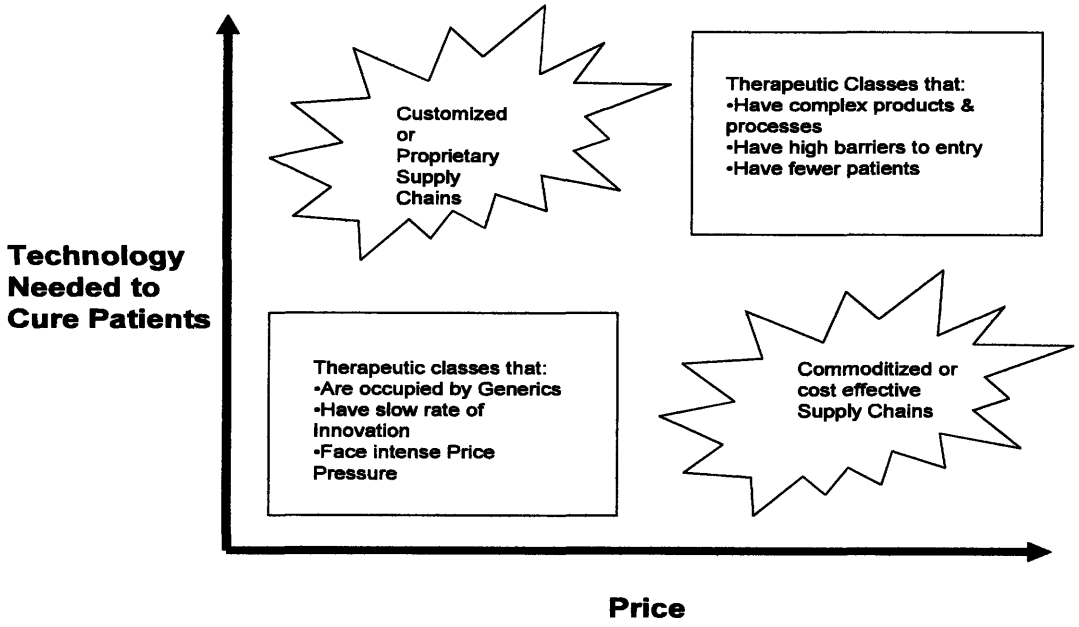

Figure 7 Expected Future Trends in Supply Chain Design

In order to support unique requirements, complex supply chains will be characterized by proprietary partnerships, which will require both trust and information sharing. For example, it might be possible to decipher or predict the drug quality by knowing the temperature patterns of drug as it makes its way to the patient in the cold

chain. The drug stability requirements are likely to result in supply chain design innovations.

In other words, to be effective, biologics supply chain and logistics design decisions will have to interface with R&D decisions to create new business models and processes. Needless to say, information technology will become important in providing appropriate capabilities to bring about the requisite structural changes within the supply chain as proposed by Lee [28]. Section 4.3 explored the possibility of development of proprietary relationships with niche service providers to achieve high entry barriers and capability requirements.

At the same time, many therapeutic classes addressing chronic illnesses will be satisfied by the generics. Fewer blockbuster drugs will be introduced due to the fact that generics are able to satisfy the needs of curing ailments sufficiently, and also due to price pressures experienced in those therapeutic classes from regulatory bodies and HMOs. For these kinds of therapeutic classes, supply chain designs will be cost-oriented. Thus, supply chains will be designed for availability during their blockbuster phases and then transition to a cost focus to compete against lower cost structures belonging to generics that often flood the market as branded drugs go off patent. Section 3.5 discussed the channel relationships for chemically-synthesized compounds.

6.2 Outsourcing of Logistics Activities

Blumberg and Lacey [3] state that Japan's largest pharmaceutical firm Takeda pharmaceutical outsourced its highly efficient logistics infrastructure of its U.S. subsidiary to its key business partners. Now, the operations are managed using electronic communication with networked suppliers. The firm claims that the new structure has

delivered benefits such as speed, quality, flexibility, insulation from business interruption, and cost efficiency. Buoyed by this success, TPNA has expanded the concept to include packaging, distribution, and warehousing functions as well. According to Chuck Whitmer, TPNA vice-president (Business Operations), "Capital saved by outsourcing can be re-channeled to R&D to support new compound development, which could improve the overall level of healthcare."

An outsourcing decision is primarily motivated by cost-reduction benefits in most cases. But it can be argued that cost reduction can also be achieved in many other ways by a firm such as effective management of activities, alignment of objectives, and redesign of processes. If pharmaceutical firms decide to retain ownership of their supply chain activities, then they have to make sure that they posses right resources and capabilities for designing and managing effective supply chains.

Before considering outsourcing of logistics function as an option, firms must answer the following questions in the short-term: do they have appropriate processes and tools to compete on cost? Have they chosen the right framework and done the right analysis? Can their current employees think in terms of reducing costs and increasing efficiency? Are the employees agile and flexible enough to adjust to the new realities at the workplace? How well do the employees execute processes and utilize tools? Are the employees cross-functional enough to break down the communication barriers?

Furthermore, the outsourcing decisions in the supply chain will also depend on understanding the resources, capabilities, and stability of the outsourcing firm. Some of the advantages that outsourcing firms can provide are: economies of scale & scope by executing modularized activities belonging to their client firms, specialized skills in

specific processes & tools, and superior execution capabilities. Generally, outsourcing firms manage continuous & repetitive activities better than many other firms. However, pharmaceutical firms will have to be aware of the fact that the outsourced activities often change and adapt to the business models of outsourcing firms over time.

To be sure, pharmaceutical firms will have to consider factors that might negate the list of positives of the outsourcing decision. Issues such as distance, culture, control & co-ordination, and quality can severely affect the effectiveness of any outsourcing relationship. It is worthwhile to investigate the impact of outsourcing on the ability to optimize the supply chain as a whole. How will the outsourcing firm interact with the pharmaceutical firms' planning & strategy departments? A loss of control will require additional effort and resources to coordinate with the outsourcing partners. The risk becomes greater as more and more activities are outsourced and new partners are included in the supply network since the supply network is only as strong as its weakest link.

In any sort of meaningful outsourcing relationship, control & visibility of activities and performance measures over time will become important decision variables. Pharmaceutical firms will have to know the outsourcing firms' future plans and why their internal processes are unique that give these firms significant competitive advantages. On the flip side, a pharmaceutical firm may also have to share their strategic and performance metrics with its outsourcing partners. Therefore, trust will be a key to the success of the relationship.

As can be seen by the discussion so far, choosing to outsource is a subjective decision and its success depends on the effectiveness of the complementary processes put

in place by both parties. As long as the pharmaceutical firm has control over the design and process flow of their operations, outsourcing of day-to-day operations to take advantage of lower labor costs and greater efficiencies might work.

It should also be pointed out that outsourced functions might not result in improved efficiencies due to coordination issues. In other words, it is very important that the outsourcing partners demonstrate that they have much better capabilities & technologies than those belonging to the large pharmaceutical firm. There have been occasions when firms such as Advanced Micro Devices (AMD) had to bring manufacturing back in house due to the limited availability of production capacity, cost-control measures, and to establish superior controls.

6.3 Operationalizing Outsourcing Decision

A significant value of logistics lies in how well a firm can restructure its operations in response to the changing conditions of the market place. Indeed, planning and control functions become extremely important in aligning activities with the changing environment. The firm should first consider optimizing the supply chain as a whole before seeking quick wins by outsourcing its operational needs. To elaborate the point further, optimizing logistics activities by leveraging freight rates, inflation, exchange rates, other cost drivers, and aligning various activities with the business strategy might lead to better alternative supply chain solutions.

Lapide [27] states that firms should not strive to emulate the best practices of others. The best practices work only under certain business conditions in certain

industries. He provides a framework that has been developed for Supply Chain 2020[7] (SC2020) initiative. According to the framework, business strategy must be aligned with the supply chain strategy and operational performance objectives specific to the company. The operational performance objectives are assessed in terms of customer response, efficiency, and asset utilization metrics and drive the operations in the desired direction set by the business strategy of the company.

Business strategy must integrate marketing, supply chain, and technology strategies. Thus, crafting a business strategy is a complex process that requires insights and acknowledgement from various functions within the firm and a common understanding to execute it well. The essence of information technology is to enable business strategy. Therefore, as business strategy evolves, information technology must evolve to support it. In the end, change management becomes an extremely critical issue when executing strategy because it is likely that a firm's employees might not understand the purpose of change and also resist in adopting new sets of procedures and tools.

Firms also have to be wary of the fact that the outsourced activities might cease to benefit them as these activities did in the past due to changing business dynamics. Fine [12] illustrates this aspect by discussing the notion of outsourcing trap where firms transform their engineers into consultants who now have to define and manage the outsourcing work. Over time, the engineers loose their hard skills and the technical solutions are then dictated by outsourcing firms. The new technical solutions proposed by the outsourcing firm might not be the appropriate solutions for the client firm.

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[7] Detailed information on the project can be found at www.sc2020.net

6.3.1 Key to Outsourcing

Reflecting on the discussion so far, it can be argued that the question that best frames an outsourcing decision for a pharmaceutical firm is: "How will an outsourcing decision optimize my supply chain as a whole and enable it to be the best in class and maximize profits?" This question will force both the pharmaceutical firm and the outsourcing firm to look beyond obvious cost reduction goals of certain activities leading to unfruitful future decisions and think about joint value creation.

To bring some objectivity to this critical decision, a firm can adopt a holistic approach to improve the quality of its outsourcing decision. The firm should think in terms of trade-offs that arise due to the current constraints and limitations in the system. This approach will allow the pharmaceutical firm to quantify the benefits of outsourcing activities to balance the loss of control & co-ordination. There are various frameworks that are available within academic institutes and professional consulting firms to explore the option.

6.4 Building an Excellent Supply Chain

The underlying driver of all frameworks is the alignment of supply chain activities with the business strategy. This fact demonstrates that firms stand to gain significant competitive advantage if they are able to figure out which supply chain models fit their business strategy best. Interestingly, all the frameworks mentioned in the literature review recognize the importance of visibility, managing uncertainty, and placing superior control and co-ordination in the supply chain. Therefore, benefits gained by applying these frameworks might surpass the benefits gained by outsourcing activities. Thus, an outsourcing decision might become inconsequential to a firm.

In summary, frameworks can be classified either as quantitative or qualitative. Clearly the adoption of these frameworks depends on a firm's orientation and expectations. However, considering the complexities involved, quantitative frameworks will have an edge over qualitative-oriented frameworks in the future.

Then, there are methodologies to enhance the operational efficiency based on Toyota production system and lean manufacturing making use of tools like DMAIC, 5S, flow charts, takt time, theory of constraints etc. Emerging frameworks are now introducing advanced operations research analytics to make these methodologies more robust, insightful, and easily adoptable to complex flows with increased throughput - Graves [18].

Also, software firms like i2 and others are selling highly integrated industry-specific proprietary supply chain solutions based on their own methodologies and frameworks. This is a natural progression for these firms to move away from standalone products to an integrated product line. It will be interesting to note how these software firms understand and align their analytics & tools to a firm's strategy. Thus, firms should understand the analytics embedded in the software vendor's tools, and whether the analytics align with firms' objectives before adopting these solutions.

7 Conclusion

The thesis concludes by stating that understanding business needs arising due to both external and internal environment, is an essential first step in finding the value of logistics in the pharmaceutical industry. We used various frameworks to understand and explore the business environment, and then map out and align the existing logistics activities with the business needs to determine the value of logistics in the pharmaceutical industry. The analysis has yielded the importance of understanding the product attributes and competitive dynamics in the design of supply chains.

There is a great degree of uncertainty associated with which technology will drive the future growth in the industry. Indeed, unique supply chain design challenges are associated with branded chemically-synthesized compounds, branded biologics, generics, and bio-similars. Branded chemically-synthesized compounds and generics fall under the umbrella of the commodity product model, whereas complexities associated with biologics suggests a mass customization model. Commodity product models are directed towards a larger target base where scale becomes important and mass customization models target smaller population. A focus on availability is extremely important for the branded drug segment, which switches to cost as and when patent expires, and generics tend to follow an extremely cost-oriented supply chain design.

Of late, designing and managing supply chains have become extremely complex and analytical undertaking. For example, Zara, a fashion apparel firm, recently adopted customized mathematical algorithms developed using operations research methodologies to improve decision-making in its supply chains. Zara's supply chain is highly customized to focus on speed that aligns very well with its chosen business model.

Similarly, the role of supply chain and logistics has gained prominence in the high-technology arena due to the runaway success of companies such as Dell. It has been noted in the press that Dell's supply chain is the primary source of its competitive advantage and plays an extremely important role in that firm's business model.

It is also important to understand that there are various frameworks available that come with their own unique process methodologies and tools. However, these frameworks tend to re-orient the firm's activities based on certain assumptions, constraints, and objectives. If the chosen framework is misaligned with the firm's business needs or is commonly adopted by firms in an industry, then the value of logistics may be lost.

Clearly, most firms will not be able to differentiate based solely on operational metrics, thus, pharmaceutical firms will have to be extremely selective in choosing the right framework and in some cases they might have to develop their own solutions to address the unique needs. Along with choosing the right framework, firms will also need to have the right resources, processes, and tools to manage the activities.

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