The Pharmaceutical Supply Chain: a Diagnosis of the State-of-the-Art
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Introduction
The MIT Center for Transportation and Logistics launched the Supply Chain 2020 project (SC2020) to examine supply chain transformations over the next few years. The guiding philosophy of the SC2020 is that the supply chain capabilities are critical for executing business strategy. And the performance of a company is inextricably linked to the effectiveness of its supply chain. Indeed, the supply chain capabilities are driven by a set of complex interplay of internal and external forces.

SC2020 is divided into two main phases that consider two very different aspects of the project. In Phase I, the emphasis is on understanding the underlying dynamics that govern the supply chain behavior today, specifically to see how supply chains are used by different companies to support their business strategies. The knowledge gathered from Phase I will be used to develop scenarios of the future state under Phase II. To this end, we investigated the pharmaceutical industry to obtain a better understanding of its current supply chain practices and its integration with business strategy.

As noted before, the structure and objectives of a supply chain are heavily dependent on multiple factors. Therefore, to limit the scope of this research, we narrowed down our focus mainly to include patented small molecule segment of the pharmaceutical industry. The general impression at the onset of the project was that due to its inherent bias for innovation, this segment is an unusual candidate for investigating supply chain practices. What we discovered during the course of investigation highlighted facts to the contrary. The more important realization was that the pharmaceutical industry is undergoing a revolutionary transformation, and in a few short years, the landscape will look dramatically different.

The Pharmaceutical Industry
The pharmaceutical industry is unique in many ways. It is essential for the well being of a society, as demonstrated by the increasingly productive and longer life spans
enjoyed by people all over the world. At the same time, due to this very reason, it is a topic of hotly contested debates revolving around its business practices. Given the very personal nature of the experience, experts and common people alike, have a very strong opinion on the effectiveness of this industry. Of late, however, the feelings among general public have been more negative than positive. There is an unrelenting pressure on the manufacturers from the managed care organizations to lower the prices of patented drugs in the United States. The experts suggest otherwise; they argue that a healthy pharmaceutical industry is critical for the development of better drugs in the future.

A closer look reveals that the patented drug segment is indeed a very complex enterprise. The cost of developing a new drug has risen steadily to reach a mark of $802 million. If the cost of marketing and launch is also included, the cost easily crosses the $1 billion level. The main reasons behind this staggering number is the increasing difficulty faced by the companies in developing new drugs; only one out of several thousand compounds reaches the clinical trial stage. To exacerbate the situation, only three out of ten drugs that are launched break even! In such a scenario, it is easy to see why drug prices keep increasing and outpacing inflation.

On the other hand, there are ample opportunities to alleviate the cost pressures by making the healthcare system more efficient. The prevalence of cost shifting between multiple entities in the healthcare industry effectively shields the inefficiencies in the system. As a result, it is very difficult to identify the pockets of non-value added activities that can be eliminated to improve performance.

An often overlooked fact about the pharmaceutical supply chain that gets masked by the pricing and innovation issues is its performance vis-à-vis safety and quality. Unlike any other industry, supply chain safety and product quality can have catastrophic consequences for the pharmaceutical industry and public in general. Consider the dense network of nodes that interact with each other to deliver a medicine to a patient. It is easy to imagine that such a supply network can be vulnerable and an easy target for introducing counterfeit products and product tampering. The pharmaceutical industry has done a good job in protecting its supply chains and keeping these problems under control. Indeed, mitigating this risk adds to the overall cost of the drug.
A bad batch of product can devastate a pharmaceutical company. In addition to the legal ramifications, the brand can suffer incalculable losses. With such severe consequences in mind, the manufacturers administer very strict quality inspection protocols to prevent quality problems. In addition, there are regulatory requirements to record and investigate any problem that can impact the quality of the product. Again, these requirements add to the ultimate cost of the product. In other words, the stringent requirements placed on the pharmaceutical companies play their part in increasing the cost of a drug.

**The Pharmaceutical Manufacturer**

We used Eli Lilly as a case study to investigate the pharmaceutical supply chain from the point of view of a manufacturer. The operating model at Lilly is fully integrated into its business strategy. The four pillars of Lilly’s operating model include innovative drugs, marketing and sales, high availability, and consistent quality. Indeed, innovation is at the heart of Lilly’s business strategy; as a result, their target market segment is not very price sensitive.

Lilly’s operating model is focused on two metrics, namely Customer Response and Asset Utilization, with more emphasis on Customer Response. In Figure 1, we show the cause and effect relationship between the operating model, operational metrics, and business strategy to maintain growth by offering innovative products.

![Figure 1: Causal Loop Diagram for Operating Model Dynamics](image)
The key business processes enabling the operating model that drives Lilly’s business strategy are:

- Capacity flexibility – planning starts 4-5 years before a drug launch to develop “manufacturing networks” using the product portfolio approach
- Inventory, Risk, & Customer Service Level - joint probability analysis to ensure 99% CSL in any given circumstance, computations also take packaging size, campaign plans, and special events into consideration
- Supply chain planning – global S&OP to create “one approved plan”
- Integrated Launch Management - single global strategy and plan that all organizations use for all supply chain related launch activities for a new drug

The Drug Distributor

We used Cardinal Health as a case study to investigate the supply chain related issues from the perspective of a drug distributor. The four pillars of Cardinal’s operating model are new products and services, warehouse network and capacity, flexibility, and buying opportunities. Cardinal has created an effective activity system around these four pillars to execute its business strategy. In Figure 2, we show the cause and effect relationship between the operating model, operational measures, and business strategy to maintain growth by extending product and service offerings.

Figure 2: Causal Loop Diagram for Operating Model Dynamics
The key processes/aspects supporting the operating model are presented below:

- offer multiple value added services to customers and suppliers
- strong purchasing team with seek-identify-plan-execute process for a buying opportunity (yield management)
- large warehousing network to ensure high availability
- working capital to exploit unexpected opportunities

**Disintegrating Supply Chain**

The four essential functions for creating a physical product supply chain include development, manufacturing, distribution, and selling. The links between these functions in the pharmaceutical supply chain are undergoing a significant transformation. We will focus on three key links in the pharmaceutical supply chain and explore them in more detail to motivate the ‘networked’ model – see Figure 3.

**Figure 3: The Evolving Supply Chain**

*Disintegration:* A majority of big pharmaceutical companies fully own the upstream link between development and manufacturing. But now, the pharmaceutical companies are increasingly outsourcing different tasks to specialized firms, such as smaller biotech firms, CROs and CMOs to maximize productivity. The biggest challenge to outsourcing growth, however, will be internal and not external. Typically, a tight control is exercised to drive R&D productivity and ensure product quality. Now, the companies will have to overcome their lack of trust in their partners and desire to control every aspect of their supply chain. Furthermore, most pharmaceutical companies consider R&D as their core competency and take a lot of pride in their R&D capabilities. It will not be easy for such companies to collaborate or outsource R&D to a smaller company.

*Disencumber:* The link between manufacturing and distribution is key from supply chain management point of view. In the current environment, the wholesale distributors dominate this space and control majority of the interaction with the end customers. As a result, the manufacturers have limited visibility into the end customer demand and requirements. As expected, the buffering of the customer from manufacturer causes a multitude of problems.
Now, the supply contracts are gradually moving away from the buy-and-hold model (inflation-based) towards the new fee-for-service (FFS) distribution model. The new model opens the doors for players, such as UPS, FedEx, & DHL that are already involved in distributing clinical-trial supplies. The ability to choose from a variety of distribution options will allow the manufacturers to become more flexible. By being more involved in the downstream activities, the manufacturers will come closer to the end customers allowing them to manage demand and supply more effectively.

Additionally, manufacturers will be able to extend their sphere of influence to touch the end customer directly - see Figure4.

**Figure 4: The Extended Reach of New Supply Chain**

*Disintermediation:* This is an extremely important link from customer management point of view. Till recently, the pharmaceutical companies had no effective means to communicate directly with their end users. The only means to promote new drugs required labor intensive process of detailing to the medical professionals. With the ability to communicate with the end customer directly i.e. DTC campaigns, the pharmaceutical companies will have more levers to manage demand and drive sales.

**A New Pharmaceutical Supply Chain Model**

We subscribe to the view that a ‘networked’ pharmaceutical model is the answer to the challenges faced by the patented drug manufacturers. According to this business model, major pharmaceutical companies will eventually perform only 40% activities in-house. Most of the remaining activities will be conducted externally, via a carefully selected, risk managed portfolio of outsourcing arrangements and strategic alliances. In fact, established pharmaceutical companies have already started moving in this direction.
The ‘networked’ model has distinct advantages over the traditional model. Indeed, the traditional model has served the pharmaceutical industry very well for a long time, but time has come to respond to the changing environment. In light of the new challenges facing the pharmaceutical industry, the key capabilities offered by the ‘networked’ model are agility, lead time reduction, rapid market access, and better resource utilization.

As an integrator, instead of developing and manufacturing drugs as they do today, the drug manufacturers of today will coordinate different expertise to fulfill demand. Such companies will create integrated supply networks by forming alliances with drug developers, clinical trial managers, manufacturers, and distributors – see Figure 5. In principle, the networks will resemble the structure made famous by Cisco Systems that revolutionized the networking systems sector.

![Figure 5: An Integrated Network Model](image)

**Drug Distribution in the future**

The recent developments in the drug distribution space make it difficult to predict the drug distribution model in the future. The scenarios that appear likely are:

- **Scenario 1**: the traditional and the latest models of today continue to coexist
- **Scenario 2**: the latest model in use i.e., IMAs replaces the traditional model
- **Scenario 3**: a blockbuster video model type arrangement becomes popular
- **Scenario 4**: a revolutionary solution enabled by a disruptive technology

Indeed, each one of the scenario will impact the structure and performance of the pharmaceutical supply chain in a unique way. The choice of model will have a significant effect on the financial and customer service performance. A high level view of various scenarios is presented in Figure 6.
Scenario 1: In case the two models continue to coexist, the service providers will be pulled in different direction by conflicting business strategies requiring two very different operating models – a situation they are faced with today. In the traditional model, speculative buying and holding excess inventory is best, whereas IMAs won’t allow hoarding of inventory and encourages a lean operation. In such a scenario, it is difficult to employ a structured approach to redesign and operate the supply chain using standard policies. In other words, this scenario represents a state of confusion for the distributors.

A recommended approach in this situation calls for separation of the two operating models and creation of two parallel supply chains. The two entities will be designed to exploit the opportunities presented by different contractual arrangements with the manufacturers in the most effective manner. It will be very difficult for the big distributors to exit the competition due to lucrative opportunities to make good profit. At the same time, the stricter and less profitable arrangements with the manufacturers will continue to pressure the distributors.

Scenario 2: From the point of view of total supply chain cost, this scenario appears to be the most expensive option. It will also make the supply chain more rigid and restrictive. The big 3 distributors will continue to dominate the space. The market forces will not be able to drive efficiency and a constant struggle for margins will plague the relationship between manufacturers and distributors. In this case, it will be difficult for the big 3 distributors to decide between staying and departing. A very likely outcome is that after some time, this model will gradually transition into Scenario 3.
Scenario 3: This scenario offers tremendous opportunity to the partners for developing creative schemes to boost their revenues and margins. This scenario will witness a proliferation of distribution service providers, consequently, the dilution of the market share of the big 3 distributors. The power of market forces will rationalize the competition and the supply chain costs will decrease. This scenario is likely to witness the fragmentation of the distribution service provider base, leading to localization of the competition. The best option for the big 3 distributors in this case will be to make an exit. Instead of competing with numerous players in this space, the big distributors will be well advised to focus on other lucrative business opportunities that will be available to them due to their healthcare expertise and availability of ready cash.

Scenario 4: This will be a huge development not only in the pharmaceutical industry but the market in general. Implications unknown!

Conclusion

Even though the pharmaceutical industry lags other industries in the application of sophisticated supply chain tools and techniques, pharmaceutical companies are executing their business strategies well by using well crafted supply chain practices. Based on our investigation, we conclude that Lilly and Cardinal, both have excellent supply chains. It should be made clear that, in isolation, most of the practices followed by these companies are basic in nature and in vogue in other industries for a number of years. The success of their supply chain system is primarily due to the tight “fit” between the supply chain processes and the business strategy. The integration has resulted in effective operating models that resonate with the respective business strategies.

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

An effective solution to manage the capacity issue in the pharmaceutical industry is to build capacity flexibility. Lilly has done a wonderful job in deploying their assets
effectively by using the concept of “manufacturing network.” Indeed, this strategy increases the complexity and cost of the system, but the benefits far outweigh the additional cost.

As a distributor, Cardinal is faced with a challenging environment consisting of demanding customers and powerful suppliers. Due to the nature of their role, there is a big difference between the strategy drivers of a manufacturer and a distributor. For a distributor, operational efficiency is at the core of its business strategy. Cardinal’s success can be attributed to its ability to execute business processes efficiently.

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

The transformation of the pharmaceutical supply chain is under way. The popularization of personalized medicine is likely to trigger dramatic changes in the traditional pharmaceutical business model. The industry will have to adjust to a new way of doing business in light of targeted medicine’s need for smaller batches of numerous SKUs. The pharmaceutical industry will move from a mass production environment to a batch production environment. And contrary to the notion of process evolution, the industry will move towards unit production as the field of personalized medicine matures. Indeed, this will be true only for a subset of treatment protocols, since many conditions, if not most will continue to respond positively to the traditional approach. As a result, we will witness the launch of parallel business models to manage different types of drugs, in turn requiring separate supply chain structures as suggested by Fisher.

Lastly, the entire drug distribution segment of the pharmaceutical industry is under a serious threat of disintegration. Based on the latest developments in this area, it
appears that there is a lot of friction between manufacturers and distributors. The new inventory management agreements, which tout the fee-for-service paradigm, are also falling short of making a dramatic impact on the pharmaceutical supply chain efficiency. The pharmaceutical industry has performed very well historically, but the model is no longer effective. The underlying dynamics of the industry are shifting and consequently, the pharmaceutical companies should respond by redefining their business strategies along with developing brand new operating models.