The Impact of COVID-19 on the Pharmaceutical Supply Chain

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Abstract

The COVID-19 pandemic has disrupted the everyday lives of people and businesses around the world, and a field greatly affected has been the United States pharmaceutical supply chain. This global pandemic has made preexisting issues within the supply chain's structure more glaring than before with people's lives being at risk. Demand for drugs is at least equivalent and likely higher in this current health setting. If companies are not providing the appropriate medications to their customers, then it can be the difference between life and death for some. To investigate the challenges behind the supply chain, the analysis was focused on problems before COVID-19, such as the lack of transparency, burdensome regulations, and logistical issues due to improper distribution. An investigation on how COVID-19 has impacted each specific part of the pharmaceutical supply chain leads to a discussion on what recommendations could be implemented to fix the presented issues. The U.S. pharmaceutical supply chain is a complex, global system that has become increasingly more challenging to navigate because of COVID-19. Shortages need to be mitigated, and the inevitability of a future vaccine for the virus needs to follow a proper logistics and distribution model to ensure its success.

Keywords
COVID-19, Pharmaceuticals, Supply Chain, Logistics.

1. Introduction

1.1 Background

The U.S. pharmaceutical industry is one of the nation's most valued industries and is one with global affluence. As of 2019, the U.S. has increased its annual spending on pharmaceuticals to more than $370 billion. That is a growth of nearly $10 billion, an approximately 2.5% increase from 2018's benchmark (HealthLeaders, 2019). Diving deeper into the spending, the U.S. represents 30 to 40 percent of the global market in per capita prescription drug spending (Ellis, 2019). The U.S. plays a sizable role in this supply chain, contributing a large amount of spending.

Not only is the US a big spender in the pharmaceutical industry, but its heavy regulations on the sector complicate matters. There is a lack of transparency among all parties involved in the supply chain that, in times of crisis, can cause significant disruption and emphasize the flaws within it. Lack of standard operating procedures and shortcuts from drug manufacturers overseas have caused the U.S. problems with drug shortages and the quality of the product to suffer. A situation like the COVID-19 pandemic has caused mass drug shortages for people in the U.S. Th COVID-19 pandemic has even forced the U.S. to bend the rules with some of their suppliers on the quality of their drugs. Drug manufacturers previously listed by the U.S. Food and Drug Administration (FDA) as not meeting standards and regulations have been now certified to meet the demand by the public due to the pandemic. The lack of drug manufacturers meeting these standards and regulations to produce quality drugs has been the product of a messy supply chain that has not been cleaned up properly. The COVID-19 pandemic is now exhibiting the flaws of the pharmaceutical supply chain. It will hopefully lead to a realization of the problems that must be fixed in an industry that affects the well-being of human lives.

1.2 Scope

For our analysis, we have elected to discuss the problems regarding the structure of the U.S. pharmaceutical supply chain. The U.S. involves suppliers all over the world, with countries like China and India being their most critical partners. In analyzing the U.S. pharmaceutical supply chain, we can consider concepts on a small scale and apply them to the global pharmaceutical supply chain or even to other countries' pharmaceutical supply chains too. The study will focus on the customer's role, the government's role, and the behavior of the pharmaceutical industry, all tied together in affecting the effectiveness of the supply chain.

1.3 Objectives

The analysis aims to show the preexisting issues with the pharmaceutical supply chain, how COVID-19 has amplified those issues, and, ultimately, how it has affected the customers who rely on an assortment of pharmaceuticals. The analysis will provide an objective view of the situation by providing the facts of the situation at hand while dissecting the structure of the supply chain to discover improvements to it while keeping the customer in mind.

2. Literature Review

2.1 Pharmaceutical Supply Chain

The United States pharmaceutical supply chain is a very complex network, covering every step from new product development to patient delivery of medications at hospitals or retail pharmacies (see Figure 1). Stakeholders in this complex system include government agencies, hospitals, clinics, drug manufacturers, drug distributors, insurance companies, retail stores, R&D companies, and the FDA. Overall, the goal of the pharmaceutical industry is to provide medications that can cure diseases, prevent infections, and maintain overall health. As of 2018, the global pharmaceuticals were a $1.2 billion industry (Prowse, 2019).
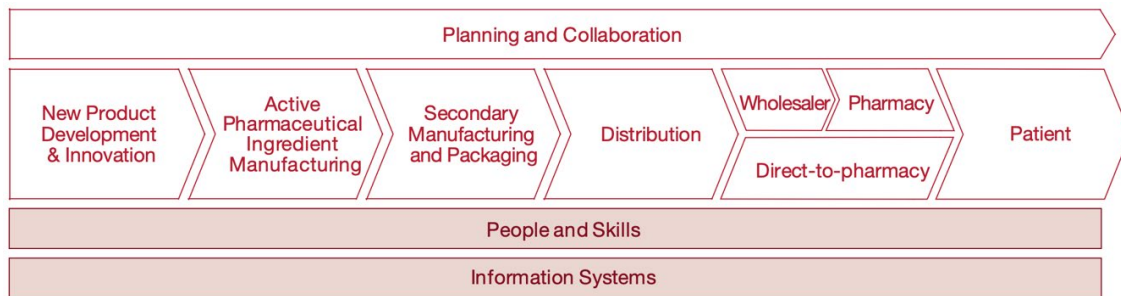

Figure 1. The general stages of the pharmaceutical supply chain (PwC, 2011).

On average, pharmaceutical companies spend 17% of their revenue on R&D costs. Clinical trials are an extensive part of Investigational Medicinal Products (IMPs), and in recent years they have expanded globally. This adds another level of complexity to the supply chain because the trials must abide by local and global regulations. Once drugs have completed all necessary testing and are ready to be mass-produced, pharmaceutical manufacturers contract out Active Pharmaceutical Ingredients (APIs) to produce finished goods. APIs must come from trusted suppliers since there are significant health risks associated with errors in pharmaceutical products. Typically, third party logistics are used to transport the APIs to the manufacturing sites. The finished goods are packaged and labeled before they are distributed to depots worldwide.

It is also imperative for manufacturers in this industry to do constant quality checks on their product lines to prevent cross-contamination or improper labeling on the final products. After the products are manufactured and packaged, they are distributed to pharmacies, either directly or through a wholesaler (see Figure 1). Nearly 80% of all drugs require temperature-controlled transportation, known as cold chain logistics. It's been reported that 30% of all cold temperature products are damaged during their shipping process (Bird, 2018). Once the products arrive at their destination, they are put into inventory. Managing inventory levels at pharmacies is difficult because patients urgently

demand the products, and the products also have an expiration date (Shoenfeld, 2019). There is a high turnover rate for products in the pharmaceutical industry, which increases the need for efficient flow throughout the entire system.

2.2 Regulating the Pharmaceutical Supply Chain

Although the United States has been able to emerge as a world leader in drug research and development, it is not leading manufacturing efforts. Most of the APIs and final goods are produced in China and India because the United States can cut manufacturing costs by 30-40% by outsourcing overseas. The FDA must closely monitor sites abroad, but this can be challenging for a variety of reasons. In recent years, quality issues with drugs have been responsible for 62% of all shortages (Pagliarulo and Lopez, 2018). As of 2013, the Drug Supply Chain Security Act (DSCSA) was put in place by the United States Congress to increase drug traceability. The DSCSA proposes that electronic product tracking and tracing be implemented into the pharmaceutical supply chain over the next ten years. It also increases the responsibility of the FDA in regulating the pharmaceutical industry.

2.3 Pre-COVID-19 Pharmaceutical Supply Chain Challenges

The U.S. pharmaceutical supply chain is a complex global system that requires producing high-quality products and where meeting demands is crucial. There are many challenges the supply chain faces in ensuring demands are met with quality and timeliness. Around 80% of active pharmaceutical ingredients and 40% of finished drug products are processed and manufactured overseas (Pagliarulo and Lopez, 2018). This importing of pharmaceutical drugs causes the adherence to FDA Regulations and transparency of the supply chain to decrease. The U.S. faces many challenges in transparency, compliance, and logistics. These issues are important to the U.S. because they cannot track the location of products in the supply chain system, whether the products are being held to the quality standards and regulations of the FDA, or whether demands are being met in quantity and in time. This ultimately leads to shortages in drug supply and low-quality goods.

2.3.1 Drug Shortages

The leading cause of drug shortages is manufacturing issues in quality and production. When the FDA finds poor-quality drugs, that medication can no longer be given to the consumer. The FDA also finds that production delays and discontinuations are becoming common in older drugs. For some pharmaceuticals, there is only one production site, and when that facility stops manufacturing a drug, there is no place else to have it manufactured. When these issues occur in manufacturing, the FDA must address the issues with the supplier (FDA, 2018).

2.3.2 Transparency

The transparency and visibility of drugs in the pharmaceutical supply chain is a massive problem in the U.S. because most pharmaceutical drugs are produced overseas, and the U.S. cannot track them. Without consistent regulations across all countries, there is no clear way for the U.S. to see where their products are throughout the Pharma Supply Chain. This causes problems because the U.S. cannot see what products are being produced when they are being produced, where their product is located, and if the product is being carried in the correct conditions. India and China are the most prominent suppliers for pharmaceuticals. The FDA is in contact with the Indian and Chinese manufactures, but they often receive little information on the current state of production at these manufacturing sites. Therefore, the DSCSA was created to maintain quality and transparency in the Pharma supply chain.

2.3.3 Compliance to FDA Regulations

With a global supply chain, ensuring compliance with specific regulations is difficult. The director of the FDA's Center for Drug Evaluation and Research, Dr. Janet Woodcock, testified to congress in 2019 that overseas production "creates vulnerabilities in the U.S. supply chain" (Blackburn, 2020). The FDA is tasked with ensuring foreign production follows Good Manufacturing Practices. However, with hundreds of manufacturing plants overseas, it is challenging to regulate production. The FDA sends quality violation notices to these manufacturers when they inspect inferior quality products, yet they cannot get these manufacturers to comply with the regulations. The FDA also has

inspectors that do routine checks at these manufacturing sites, yet the sites still will not cooperate with the rules. The FDA must also ensure that shipping and distribution follow all regulations as well.

2.3.4 Logistics Challenges

Logistics is also a considerable challenge in the Pharma supply chain. Ensuring that products are delivered safely and promptly is crucial to many people's lives that depend on pharmaceutical drugs. It is vital to regulate the supply chain to make decisions on delays, quality inspections, and customer needs. A critical example: some hospitals will not let a patient receive treatment until they know they have all the medication needed in stock; other hospitals might start treatment, knowing that the drug will be delivered soon. Therefore, shortages and delays are not acceptable in the pharmaceutical supply chain and why transparency is so important.

3. Pharmaceutical Supply Chain and COVID-19

3.1 New Products

COVID-19 is slowing new pharmaceutical product development due to material shortages, disruptions in clinical trials, and backups in FDA approval. As discussed in the next section, the outbreak in China and India has caused disruptions in the supply of active pharmaceutical imports (APIs). Since APIs are key to production, a GlobalData analysis found over 50 drugs at risk of adverse manufacturing effects. Since drugs going through clinical trials are manufactured with the same supply chains, the ability to execute them is at risk (Nawrat, 2020). In-person trials are challenging to comply with social distancing methods for reducing the spread of the virus. As such, additional safety measures are required. Implementation of safety measures, including virtual trials, take extra time to set up (Licholai, 2020). Some companies have already elected to pause or cancel clinical trials (Nawrat, 2020). With the priority of developing lifesaving drugs both for the pandemic and for other maladies, the FDA will probably postpone less critical drug approvals to prioritize its limited resources. Thus, the time for new drugs to get to the market will be extended (Liu, 2020). With the combined effects of strain on the API supply, difficulties with clinical trials, and extended FDA approval time, the COVID-19 pandemic appears to be hindering the development of new pharmaceutical products.

On the bright side, many of the factors that are slowing most new products are promoting the rate of development for COVID-19 vaccines, tests, and other products. According to an article from the Yale Insights, relevant agencies from the U.S., Europe, and China are all fast-tracking approvals for clinical trials in hopes of expediting the development process (Licholai, 2020). While COVID related developments may also be subject to the same material and production restraints as other drugs, the global prioritization towards a solution benefits COVID drugs for the same reasons that the development of other medications is hindered.

3.2 Active Pharmaceutical Ingredients

The availability of active pharmaceutical ingredients (APIs) has been a source of strain on drug supply chains. Most API production occurs outside of the U.S., at around 90% (Foley, 2020). The most significant contributors to API production are sourced from China and India, as they have a high volume of raw materials. With the outbreak in China, production was shut down at most plants temporarily in January and February but was back up in March (Mullin, 2020). India experienced similar issues as China with a lockdown at one of their manufacturing hubs. While production is back up now, the disruption in production highlighted the dependence of the United States on supply from China and India. As a result, people in the United States are calling for shifts to domestic production in the event of further disruptions in international supply (Liu, 2020). However, the market forces, availability of raw materials, and reduced flexibility involved with drug production is unlikely to allow for an immediate change in the supply chain. The pandemic has shown the need to have a robust supply chain to allow for continuity during disruptive events where there are multiple sources for key components, and there are sourcing objects from multiple regions to prevent the dependencies highlighted by the pandemic (Mullin, 2020). While the pandemic has not caused significant disruptions to the overall supply of APIs as of this point, it has shown the weaknesses in the current drug supply chain and proved the need for having a robust chain.

3.3 Distribution

In the current state, backup supplies for about a month or two exist at most large pharmaceutical companies. Still, there are disruptions in the ability to keep up with distribution when panic buying trends are seen (Scipioni, 2020). Distribution efforts are also shifting largely to at-home delivery processes like online pharmacies and assistive apps as customers are more likely to stay home and avoid in-person pharmacies to prevent infection (Gillbraith, 2020).

Many concerns in distribution, however, are focused on the potential for distribution of potential vaccines or those drugs that could assist in treating COVID-19. Once a vaccine is produced, there is concern about handling the logistics to transport mass numbers promptly across the world. This could potentially be handled by the private sector and/or by the government, as there could be government public health funding to aid in this quick mass distribution (Armstrong, 2020). Not only that, but the distribution workers may be more limited due to financial impacts, illness, and social distancing measures (Gillbraith, 2020).

3.4 Pharmacies

Pharmacies are at the frontline of the pandemic and critical to maintaining public health. Ken Thai, PharmD, president of the California Pharmacists Association (CPhA), wrote, "As patients, their families, and communities work together to "flatten the curve" amidst the COVID-19 pandemic, access medications to treat chronic diseases, behavioral health conditions, and over-the-counter symptom management is vital." (Ientile, 2020). Many pharmacies and pharmaceutical companies saw initial panic buying trends, impacting sales (Sagonowsky, 2020). However, Johnson and Johnson's representatives stated that they were expecting these trends to go away by the end of the year (Sagonowsky, 2020). Trends have also shifted towards online delivery systems (Gillbraith 2020), which has been reflected in measures such as CVS Pharmacy waiving charges for home delivery (CVS Health, 2020).

The CDC has recommended that pharmacies make changes such as requiring all customers, pharmacists, and pharmacy technicians wear a mask, postpone delivery of vaccinations and similar face-to-face clinical services (CDC 2020). Minimizing contact between staff and customers with plastic barriers, increased cleaning procedures, and social distancing protocols are also recommended, impacting the daily procedures of pharmacies. Additionally, some pharmacies are assisting in COVID-19 testing (CDC, 2020), putting staff in close contact with potentially infected people. Many pharmacies are also preparing to be ready when vaccines can be administered (Ientile, 2020).

3.5 Customer

Customers' access to medications has been impacted. Customers may be forced to switch to telehealth services or to utilize mail order or drive through systems for prescription pick-ups (American Society of Transplantation Transplant Pharmacy Community of Practice, 2020). Drug shortages have occurred in multiple products, causing a variety of outcomes. In some cases, pharmacists can work with patients to determine alternatives, as most significant prescriptions have various brands through different drug companies (Scipioni, 2020). However, due to the limited supply of drugs utilized in hospitals for treating COVID-19, some less-than-ideal options are being utilized. For example, Propofol, a sedative, is seeing extreme shortages, leading to the use of benzodiazepines that can cause ICU delirium in patients. Additionally, some opioids are being used at higher rates, leading to more potential for misuse (Davies et al., 2020). There are also regional shortages of albuterol inhalers, and the American College of Allergy, Asthma, and Immunology stated that "the shortage is occurring because of the increased use of albuterol inhalers in hospitals for COVID-19 and suspected COVID-19 patients of helping with respiratory issues." (Llamas, 2020). These shortages, among others, have implications for those infected by COVID-19 as well as the general public.

4. Recommendations

4.1 Manufacturer Balance Across the Globe

Though the industry is wary of the future effects of COVID-19 that will ripple through the supply chain in the coming months, the production of pharmaceuticals seems to be continuing without the disaster initially feared. However, a

new fear has spawned in its place. Countries across the globe are now turning their attention to their dependence on a few other countries to produce their pharmaceuticals, namely China and India. These two dominate as the main suppliers of APIs and found themselves caught in the heat as closures of their manufacturing facilities panicked their customer countries. Though the situation was handled quickly enough to continue production and avoid mass shortages before they could happen, the U.S. will likely implement initiatives in an attempt to balance the production of crucial pharmaceuticals across the globe and reduce the risk of a shortage in the future events.

4.2 Distributor and Pharmacy Contingency Planning

Even though the production of pharmaceuticals weathered the storm, there are still issues within the distribution and retail sectors of the pharmaceutical supply chain. Transportation companies have felt considerable hits to their workforce as the virus disallows many to show up for work and discourages others from continuing to work despite their current good health. Without these transportation operators, drugs cannot be distributed to the pharmacies. Additionally, pharmacies are sprinting to create and implement safe methods of getting medications to their customers. Moving forward, contingency plans for disasters such as the COVID-19 pandemic must address these problems. A "Plan B" for transportation companies that ensures the safety and health of their drivers as they transport drugs is critical, as is the implementation by pharmacies of safe product pick-up methods like contactless delivery. Each of these plans will be necessary as a vaccine for the virus is released and ready for distribution throughout the U.S.

4.3 Advice for Customers

In realizing the reality of the current pandemic, customer buying habits evolved into panic-buying, leaving those who did not partake without any supply for themselves. Though customers cannot control the choices of anyone other than themselves, some actions can be taken before a disaster occurs to increase their safety throughout it. A customer may consider keeping a reasonable, additional amount of their critical drugs on-hand. If already amid a disaster and the customer was not able to take that precaution, they may work with their doctor or pharmacist to determine an alternative. Specifically, in the case of COVID-19, the customer should opt for obtaining their medication through methods that decrease their contact with others, such as ordering online or over the phone and requesting a contactless delivery to their home.

5. Conclusion and Moving Forward

The COVID-19 global pandemic has highlighted several glaring problems that, when considered together, amount to a high risk for failure in the pharmaceutical supply chain. Though there has not yet been a critical shortage of drugs due to manufacturer shutdowns, the act of the shutdowns themselves may be enough to push the United States to reconsider its dependency on just a few countries to supply the necessary materials and labor to produce drugs for U.S. citizens. To make matters even riskier, those same few countries lack communication and transparency regarding their processes, leading to quality issues that further constrain the supply available. Within the transportation and delivery sections of the supply chain, there has been a massive struggle to meet the needs of customers, with so many service workers falling ill or refusing to work under the current pandemic conditions. Once the drug a customer needs becomes available, the customer must be provided with and accept the opportunity to receive their products safely without unnecessary risk of exposure to infection. All agents within the pharmaceutical supply chain must acknowledge these problems, and their accompanying risks, as well as, consider the proposed recommendations if they are to protect the supply chain and allow for continued growth in the future.

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