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EXPLORING THE ISSUE OF DRUG SHORTAGES IN THE U.S. AND THE IMPACT IT HAS ON THE HEALTHCARE INDUSTRY

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EXPLORING THE ISSUE OF DRUG SHORTAGES IN THE U.S. AND THE IMPACT IT HAS ON THE HEALTHCARE INDUSTRY

by

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ABSTRACT

EXPLORING THE ISSUE OF DRUG SHORTAGES IN THE U.S. AND THE IMPACT IT HAS ON THE HEALTHCARE INDUSTRY

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The idea of American hospitals running out of medicine was not perceived to be possible, but it is a current reality. The impact of high demands and low supplies of some drugs has delivered a tough financial blow to healthcare facilities. In recent years, the number of recorded drug shortages has continuously grown and has created challenges in the healthcare industry. Delayed treatments, adverse outcomes or even death, with the use of alternative medicine have led to patients being negatively impacted. The reasons for drug shortages are multi-faceted, ranging from manufacturers challenged by FDA inspections to inadequate access to raw materials sourced internationally. Although permanent and sustained solutions are still pending, facilities have taken interim actions to manage the problem internally. Furthermore, laws have been pursued to force manufacturers to communicate anticipated drug shortages by key stakeholders like the

Food and Drug Administration and healthcare facilities.

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CHAPTER 1

GROWTH OF MEDICATION SHORTAGES

1.1 Background Information

Something that might come as a shock to most people, is that the United States has been experiencing drug shortages at an increased rate over the past decade. A drug shortage occurs when the demand for medications becomes higher than the supply available. This information is not common knowledge to the general public, but it is certainly well known in the healthcare industry. This type of problem puts a significant amount of burden on the healthcare providers because they are expected to be able to provide for their patients. Hospitals do their best during these shortage phases to stay on top of the demand and not worry the patients, but such a problem will not stay hidden for long. There has been multiple news coverage on the subject over the years and this has increased public awareness on this growing issue.

The Food and Drug Administration (FDA) is responsible for keeping up with the statistics of these drug shortages, but they can only rely the information that is given to them to stay informed of the full impact of these shortages. During the years 2010 and 2011 the number of recorded drugs with shortages was at an all-time high with 211 and 267 respectively (Traynor 2011). However, these numbers only represent the incidences that were reported to the FDA, so realistically, the true shortage numbers are actually higher than is reported.

Over the past few years the drug shortage numbers have reduced dramatically, but there is still a lot of work to do in order to alleviate this issue (Figure 1.1). Overall, the number of recorded drug shortages increased significantly from 2009 to 2011, but soon tapered off and remained relatively the same when comparing 2012 to 2015, which is a step in the right direction (Figure 1.1).

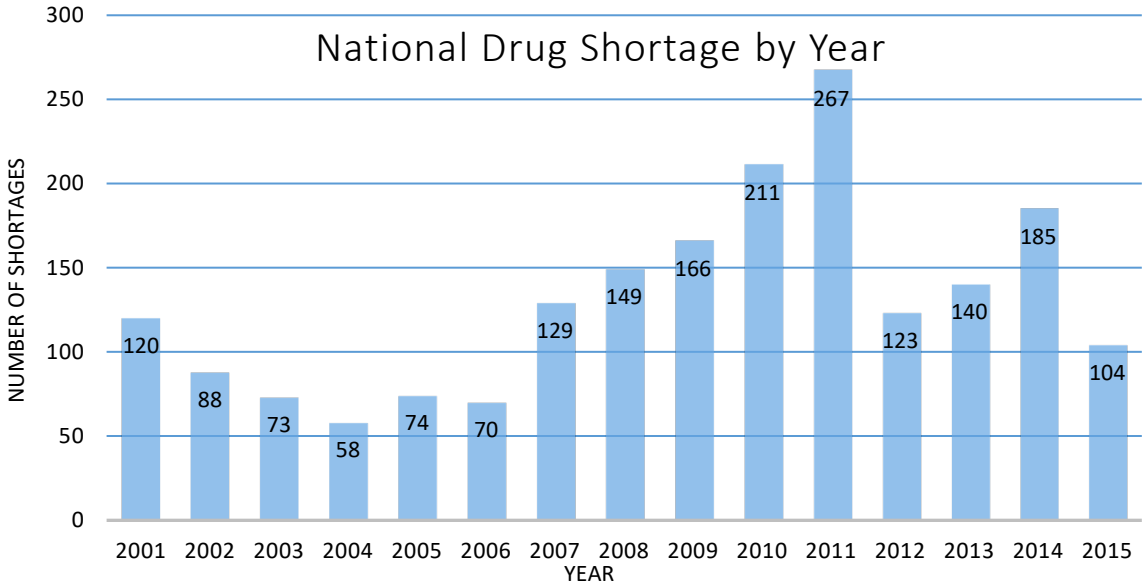

Figure 1.1: National Drug Shortages

1.2 Types of Drugs Facing Shortages

According to Premier Inc., a healthcare performance improvement alliance of about 3,600 U.S. hospitals and over 100,000 other providers, 77% of drug shortages are injectable drugs. Injectable drugs are the fastest method of getting the medicine directly into the bloodstream.

Shortages of these drugs have caused a variety of issues in many different areas of the hospitals systems (Traynor 2011). One of the impacted area is the anesthesia & operating room. It would not be possible for surgery to be done without the critical role of

anesthesia. Another area affected by this is oncology. Cancer is very prevalent in the United States, and with the shortage of necessary medications, many patients will have delayed chemotherapy and other treatments.

Analgesic and antimicrobial agents are also in low supply right now. These agents are medicines given to patients to relieve severe pain and to fight off bacterial infections respectively. Emergency drugs, like the medicine used to stop cardiac arrest or an allergic reaction, are also in short supply (Susman 2011).

As one can imagine, the high demand and low supply of these drugs can and will have a tremendous influence on the efficiency of hospitals, and their ability to provide adequate care. There are too many drugs to list individually, so they are categorized by their drug class. Over the last five years, the drug class with the highest number of shortages was the Central Nervous System category (CNS), and the class with the least was the Eye, Ear, Nose, and Throat category (EENT) (Figure 1.2).

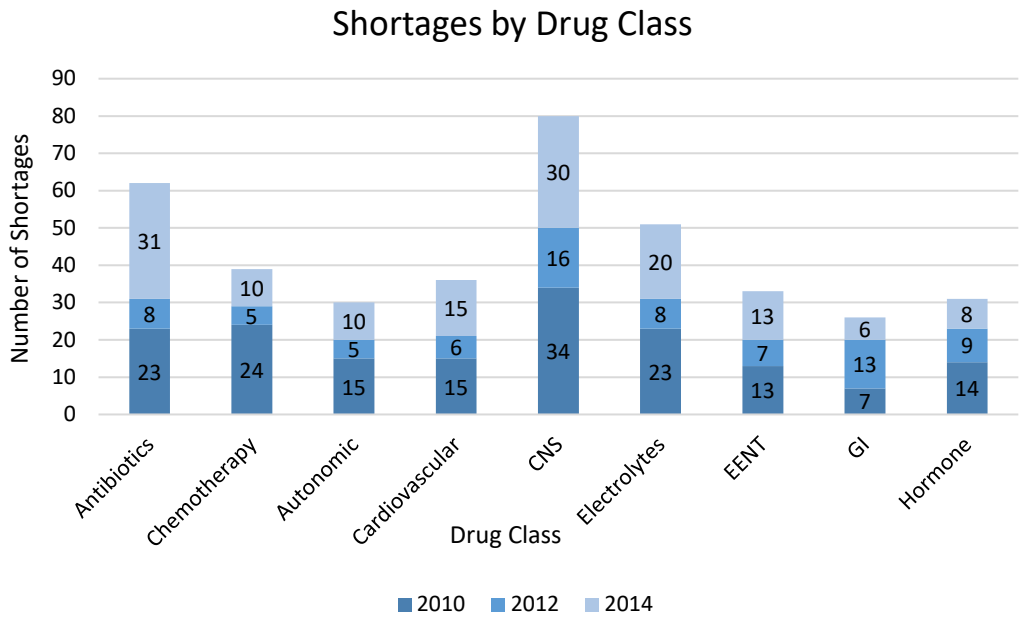

Figure 1.2: Shortages by Drug Class

1.3 Reasons Why the Number of Shortages are Increasing

There is not a definite answer to this question, because the answer will change depending on who you ask. According to research done at the University of Utah issues with raw materials only covers 2 percent of the blame. The areas of business decision, supply and demand, and manufacturing problems contributes to a little more than half of the reasons why drug shortages exist. The most interesting finding is that the major reason for drug shortages is still unknown (Figure 1.3). There are many different factors that contribute to this problem but how big of a role each factor plays in the overall challenge is yet to be determined (Traynor 2011).

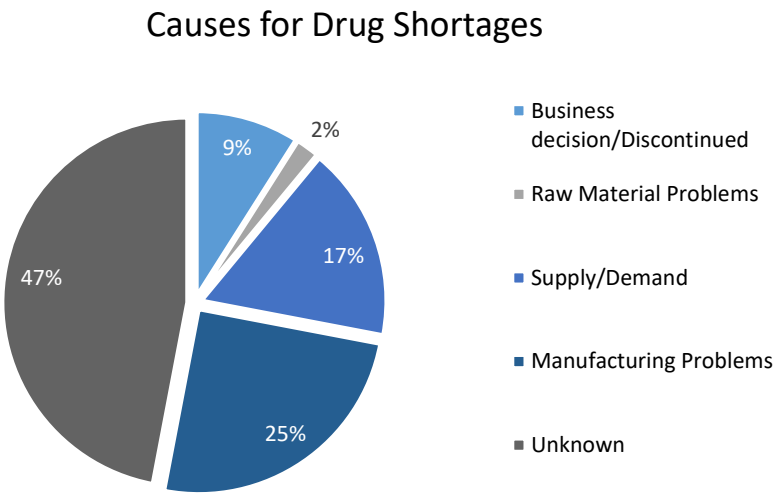

Figure 1.3: Causes for the Drug Shortage

1.3.1 Different Factors

1.3.1.1 Manufacturing

A lot of pressure is placed on the manufacturers of the medicine to keep up with the demand. As with any company, workers are expected to follow and abide by the rules

given to them. If the FDA does not believe that a factory is in compliance with their rules, the facility can be subjected to inspections (Drug Shortages Cost 2011). These inspections will lead to a temporary production halt, and depending on what needs to be fixed or improved, the factory can be closed for several weeks at a time. When the factories are already facing a drug shortage the problem is compounded, there are always delays bringing the production back online (Fox et al. 2009).

1.3.1.2 International Problems

A lot of the raw materials used to make the needed drugs here in the United States come from foreign countries (Fox et al. 2009). There are many different reasons why this contributes to the current drug shortage. The overall quality of the materials has been placed under question with the discovery of counterfeit rings. Counterfeit rings are companies who manufacture and sell fake drugs. There has been many instances where these counterfeit rings were caught smuggling or importing fake drugs across country borders (Putze et al.). The fake drugs are identifiable because of their unexpected negative side effects that are sometimes life threatening.

Another problem faced between countries is the potential of political disputes. An example of this is with the drug Sodium Thiopental that is commonly used in the initiation phase of general anesthesia. This problem led to Hospira Inc., the world's leading provider of injectable drugs, to withdraw from the Thiopental market. Thiopental is manufactured in Italy, and the Italian government refused to export to the U.S. because it is used in many states to induce unconsciousness in prisoners before getting lethal injections. The Italian government is against the death penalty, and they did not want their facilities to be at risk

of any liabilities (Koppel 2011). To solve this issue Sodium Thiopental has been widely replaced with Propofol.

There is the rare possibility of a natural disaster occurring that cannot be foreseen or avoided. Disasters such as fires, hurricanes, floods, or tornadoes can destroy factories that can prevent the transportation of the materials to the United States. This occurred in 1998 when hurricane George caused damages to manufacturing facilities in Puerto Rico that resulted in shortages of several drugs (Fox et al. 2009).

1.3.1.3 The Law/Government

Presently there is only a limited amount of regulation in effect that deals with drug shortages. Manufacturers are only required to give a shortage notification if they are the sole source of the medication, and there is no consequence for failure to notify even if they are the sole source (Conde 2012). There is no sense of responsibility placed on the manufacturers because they are not obligated to report information, such as reasons for shortages or how long they expect shortages to last.

1.3.1.4 Food & Drug Administration

According to the U.S. House of Representatives Committee on Oversight and Government Reform, "Although the shortages have been attributed to a myriad of factors, from a lack of raw materials, to increased demand, information obtained shows that the crisis was largely sparked by actions of the Food and Drug Administration (FDA)." The Committee learned that because of FDA regulatory activity and interventions, 30% of the total manufacturing capacity of four of the largest American generic injectable medication producers: Bedford Laboratories, Hospira Pharmaceuticals, Sandoz Pharmaceuticals, and Teva Pharmaceuticals, had been shut down. According to the American Society of Health

System Pharmacists (ASHSP) shortage list of February 2012, 58% of the 219 drugs on the list were there as a result of factories undergoing FDA clean-ups. Upon further investigation, it came to light that the reasons behind the shut downs had nothing to do with the drugs harming customers. Since these instances were not a threat to public health, the FDA should have found another way to address their issue without disrupting the entire facility (FDA's Contribution 2012).

1.3.1.5 Inventory Practices

This factor may seem minor compared to others, but over time it accumulates and can have a big impact on the matter. One would hope that hospitals would be considerate of one another and only buy what is needed and not buy in excess, but the reality of the situation is that they will only look out for themselves. Many hospitals will go and buy up the medicine in stock and hoard them in storage. When this happens, the supply of drugs available to all hospitals is reduced to almost nothing. This leaves other hospitals to fend for themselves, struggling to find other options to avert any crises that may occur (Fox et al. 2009).

CHAPTER 2

RISK TO MEDICINE SAFETY

2.1 Medication Error Risks

During a drug shortage, health care providers and patients face increased risk. When comparing types of patients, there is double the risk to children than to adults. Research has shown that children are more prone to harm because of their fragile state (Kaushal et al. 2001). While hospitals are facing the shortage, they have to find some way to continue caring for their patients, and that usually means the introduction of alternative/unfamiliar medications. There are a number of things that could go wrong in the process of finding and using such medicine.

Figure 2.1: Introduction of Different Risks

The first step for hospitals is to find an alternative medication to replace the drug that is in shortage. When a suitable replacement is thought to be found the next step is to locate it (Figure 2.1). If the drug cannot be found in the United States, it will have to be found internationally. As stated earlier, there are numerous reasons why this step could postpone the attainment of the drug; like natural disasters and political disputes. If the hospitals cannot obtain the medication in a timely fashion, they may be subject to delay or even cancel treatments set up for their patients, which leads to a longer recovery time. A possibility that is not without its dangers, is using expired medication when they have no other option (Conde 2012). Hospitals must ask the patients if they are willing to go down that path or not. Even if hospitals are lucky enough to find and acquire the medicine they need, they still face risks. The new drugs may have suboptimal outcomes when compared to the original drug (Traynor 2011).

Another area that needs close attention is medicine dosage. What might have worked for one drug may not work for the other. If nurses and physicians are not paying attention to this very minor but really important factor, their patients could have negative side effects that could lead to catastrophic events.

An error that could happen at any time, not only related to a drug shortage, is the possibility of contamination. If hospitals are not keeping up with the storage of the medicine, or using clean vials and instruments, a mixture of the drugs might occur.

2.2 Examples of Real Life Stories

The risks that were mentioned earlier are not hypothetical events. There are many incidences where patients have dealt with the negative consequences that come with drug

shortages. Most of the time it is a result of having to use a substitute drug that may or may not have the same results.

During a time when Morphine was not available, hospitals used a drug called Hydromorphone as a replacement. Hydromorphone, which is seven times stronger than Morphine, was accidentally delivered to some patients at a morphine-level dosage. This led to two deaths and several naloxone interventions, a reversal of opioid overdose. This shows how important it is for physicians and nurses to know all the facts about the drugs before they prescribe it to their patients.

Bacterial infections are sometimes fought off with the drug Amikacin, and when not accessible, alternative drugs were used. This switch in medicine caused the death of one patient and another was readmitted to the hospital when the antibiotic could not affect the resistant organisms in the body (Susman 2011).

Propofol is a very important drug used mostly by anesthesiologists. Substitutes for this anesthetic drug resulted in inflammation of the veins, prolonged nausea and vomiting, and difficulty weaning patients from the breathing tube after the surgery was completed.

There are many other negative anecdotes due to drug shortages. This problem has led to numerous deaths and unwanted consequences, like physicians having to ration critical drugs and triage their patients (Traynor 2011).

CHAPTER 3

ACQUISITION OF MEDICINE DURING DRUG SHORTAGES

There is a certain process that pharmacies of hospitals follow in order to get the medications they need. This process is very straightforward, but when manufacturers are in the middle of a drug shortage, the normal flow of things is disrupted. Usually when an order is placed from the hospital's pharmacy to the wholesalers, there is not a problem confirming and delivering the order (Figure 3.1). However, when a product is on back order, or is no longer in stock, wholesalers are forced to deny the order, and the hospital must try an alternative product or find someplace else to get what they need (Figure 3.1).

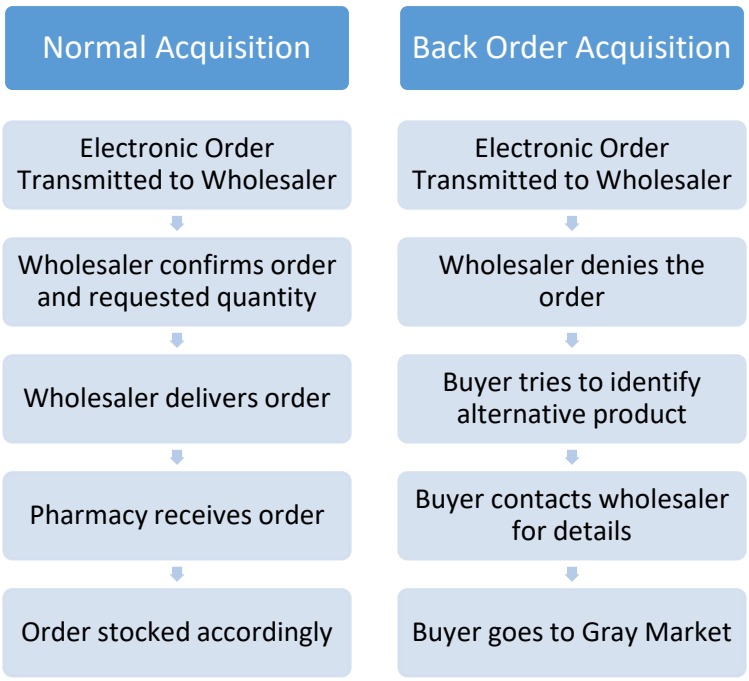

Figure 3.1: Comparison of the Acquisition of Drugs Process

3.1 The Gray Market

Hospitals sometimes have to resort to acquiring desired medication through not so conventional means, like the gray market. The gray market is a name given to a market that is based upon goods sold by unauthorized dealers outside of their "authorized" channels of trade. An example of this would be a man buying the last tickets available for a concert, and turning around and selling them at a much higher price. If the buyer really wants to go to the concert, they will have to pay the increased price, but also take the chance that the tickets are counterfeit. The same thing happens in the healthcare world.

During times of scarcity, people set up fake pharmacies and stock up on the drugs to sell at a huge mark up (Investigation 2014). Anyone can set up an independent pharmacy, all they need to do is acquire a license with a state board of pharmacy and sign a contract with a primary wholesaler (Tomsic 2013). In the gray market, those contracts are usually broken. A licensed pharmacy in North Carolina called LTC Pharmacy was recently found to be guilty of this practice. This pharmacy was purchasing drugs that were in short supply and then transferring them to International Pharmaceuticals, a licensed wholesaler that sold the drugs in the gray market. The most interesting thing about this story was that both companies have the same owner and were located in the same building (Investigation 2014).

Figure 3.2: Pictures of a Fake Pharmacy Set up in the Gray Market

Usually when hospitals buy medication from the gray market it means that they have exhausted every other source and have come up with nothing. There are many risks when purchasing drugs through the gray market. Since most of the companies are fake and can appear like the pictures above, they may not know how to handle or store the products properly. There have been incidences where medications were found to have been altered or contaminated. Even stolen and counterfeit drugs have been sold in the gray market.

In some states it is mandatory that every medication must be accompanied by a drug pedigree. A drug pedigree is a document that provides data on the history on a particular batch of drugs, container size, and the name and addresses of every place involving the drug. An example of a drug pedigree can be seen in Appendix A.

Even though the practices of the gray market are not prohibited by law, hospitals and pharmacies still need to be careful with whom they do business. Patients put a lot of trust in hospitals to provide the best for them, and by utilizing the gray market, threats to the patients increase tremendously.

CHAPTER 4

THE FINANCIAL IMPACT

So far, the only risks that have been mentioned were the ones that affect patients; however, they are not the only ones facing threats. Since hospitals have nowhere else to turn to during times of a drug shortage, the gray market is usually the only option left. Making money is the main focus of most companies, and the vendors involved in the gray market are no different (Drug Shortages Cost 2011). Dealers are able to set their desired prices, since they are the only ones with the product the hospitals need. These prices are marked up substantially, and hospitals have no choice but to pay if they want to provide for their patients (Figure 4.1).

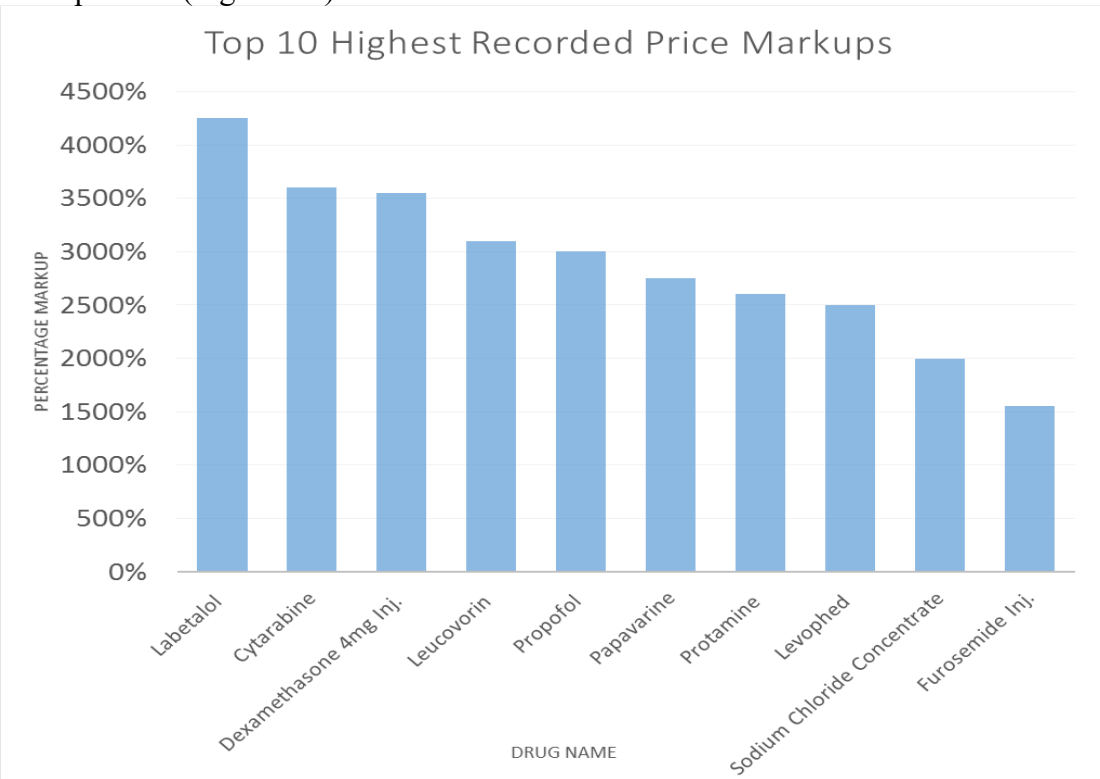

Figure 4.1: Examples of the 10 Highest Recorded Markups by Drug Name/Care Category

A hypothetical scenario indicating how much hospitals are forced to pay can be seen by comparing the annual cost of medication during a normal year and when drugs are on back order. During a year of normal drug production a hospital will pay about $212,000 for the top fifteen drugs that are at the top of the back order list. When they purchase the same drugs during a drug shortage through the gray market, they may end up paying around $1.4 million annually. To put that into perspective, all the hospitals in the Unites States spent about $200 million in 2010, one of the years with the highest number of recorded drug shortages (Drug 2011). Something to keep in mind is that these numbers do not include the expense associated with clinical and operational labor.

CHAPTER 5

SOLUTIONS TO THE PROBLEM

The huge dilemma of drug shortages is one that needs to be fixed as soon as possible. However, there is no quick fix solution, so whatever solution is proposed is going to take some time in order to see any results. There are so many different participants in this situation, ranging from the manufacturers, hospitals, to the government, and they each have a vital role. They need to take responsibility for their actions and unite to provide a resolution.

5.1 Risk Reduction Strategies

5.1.1 Research

Hospitals should not be blindsided by the arrival of a drug shortage. Being prepared is the best defense hospitals can have against such a situation. A couple of staff members should be assigned to regularly research the state of drug production. They can always check with their wholesaler and manufacturers to be informed, before things get out of hand. Research should also be done on potential therapeutic alternatives to medications that may be in low supply in the future. Knowing where to purchase these substitute drugs will help hospitals not waste precious time.

5.1.2 Evaluation

Regular inventory checks are also a good idea, so hospitals are aware of what they have and what they need. As stated before, having the alternative medication in stock will save time and money if a drug shortage does occur. A drug

shortage does not affect only one hospital, it affects all hospitals nationwide. When hospitals are trying to prepare for the worst and begin stocking up on the medication, they need to keep in mind that hoarding and over stocking is only beneficial to them alone.

The use of drugs in hospitals also needs to be evaluated. This idea parallels waste reduction. Physicians and nurses need to make sure the drugs are being used in the most appropriate way, like making sure that medications are not being used extensively. That might mean that patients need to be prioritized, from need the drug the most to maybe another drug can be used, or making sure that the lowest feasible dose can be used without putting the patient's health in danger.

5.1.3 Communication/Relationships

With any job, communication is key. Good relationships are built on good communication. Sometimes hard feelings can rise between the hospital's pharmacy and physicians, when drugs cannot be provided. That is why information systems need to be kept up to date so this type of conflict does not occur (Drug Shortages Cost 2011). It does not help anyone if manufacturers are slow to communicate production output to wholesalers and the hospitals.

5.1.4 The Gray Market

Hospitals should do everything in their power to stay away from the gray market at all costs. Sometimes there may not be any other option, so if the gray market must be used, hospitals need to use precaution. It is known that drugs bought through the gray market sometimes end up being contaminated or even fake, so in order to avoid purchasing these types of drugs, hospitals need to enforce the necessity of documentation of

authenticity, like a drug pedigree. Hospitals and pharmacies can use this document to verify the legitimacy of a drug before buying it.

5.1.5 The Government

There has been some effort put forth by the government, and so far it has positively impacted the situation. As of October 2011, the Obama Executive Order requires that the FDA must expand current efforts to expedite any inspections being done on manufacturing factories to accelerate the reopening of the facilities. Under this order, the House of Committee on Oversight and Government Reform had to start investigating the gray market. Right now the activities going on in the gray market are not considered illegal, just unofficial.

The FDA has also made its own efforts to reduce the prevalence of drug shortages. Manufacturers are required to report the emerging potential of a drug shortage six months in advance, to avoid being fined (Drug Shortages Cost 2011). Since everyone wants to make money, it is in the best interest of the factories to comply with the new rule to avoid these expenses.

The challenges that come along with the increasing frequency of drug shortages will always exist. There is no way for hospitals or pharmacies to predict and plan for every drug shortage, but careful preparation can help avoid subsequent problems from turning into a major crisis. That is why it is so important to establish an effective drug shortage management plan with clear guidelines and procedures if and when this issue occurs again.

APPENDIX A

EXAMPLE OF A DRUG PEDIGREE

_____ *(Wholesaler's name)*

PRESCRIPTION (LEGEND) DRUG PEDIGREE
History of Drug Sales and Distributions

Legend Drug Name, Strength, Dosage Form, Container Size: _____
☐ This is a repackaged drug (requires repackager's pedigree information and authentication of repackager's pedigree)
NDC (optional): _____

Lot Number	Quantity	Unique Serial #

Reference* Number: _____
Document Type: _____
Reference* Date: _____

(related to the sale by the wholesaler identified above)

OWNERSHIP HISTORY

PHYSICAL DISTRIBUTION HISTORY
(if different from the owner information)

Manufacturer's Name: _____
Manufacturer's information for authentication: _____
1. Wholesaler that purchased from the MANUFACTURER or a REPACKAGER *(which requires authentication)*

Name: _____ Address: _____ _____ Date Purchased & Ref* #: _____ Print Name of Recipient: _____ Signature of Recipient: _____ Name of Authenticator: _____ Signature of Authenticator: _____ *To authenticate a subsequent transaction, contact:* Name: _____ Telephone Number: _____ Email address: _____	Name: _____ Address: _____ _____ Date Purchased & Ref* #: _____ Print Name of Recipient: _____ Signature of Recipient: _____ Name of Authenticator: _____ Signature of Authenticator: _____ *To authenticate a subsequent transaction, contact:* Name: _____ Telephone Number: _____ Email address: _____
2. #1 Above SOLD TO: Name: _____ Address: _____ _____ Date Purchased & Ref * #: _____ Print Name of Recipient: _____ Signature of Recipient: _____ Name of Authenticator: _____ Signature of Authenticator: _____ *To authenticate a subsequent transaction, contact:* Name: _____ Telephone Number: _____ Email address: _____	SHIPPED TO: Name: _____ Address: _____ _____ Date Purchased & Ref * #: _____ Print Name of Recipient: _____ Signature of Recipient: _____ Name of Authenticator: _____ Signature of Authenticator: _____ *To authenticate a subsequent transaction, contact:* Name: _____ Telephone Number: _____ Email address: _____
3. #2 Above SOLD TO: Name: _____ Address: _____ _____ Date Purchased & Ref * #: _____ Print Name of Recipient: _____ Signature of Recipient: _____ Name of Authenticator: _____ Signature of Authenticator: _____ *To authenticate a subsequent transaction, contact:* Name: _____ Telephone Number: _____ Email address: _____	SHIPPED TO: Name: _____ Address: _____ _____ Date Purchased & Ref * #: _____ Print Name of Recipient: _____ Signature of Recipient: _____ Name of Authenticator: _____ Signature of Authenticator: _____ *To authenticate a subsequent transaction, contact:* Name: _____ Telephone Number: _____ Email address: _____

I swear or affirm that the information contained on this pedigree is accurate and complete and that prior sales and distributions have been authenticated, if required.

_____ _____ _____
Signature (authorized to bind the company) Print Name and Title Date

Page ____ Of ____ Pages.

* Reference Number should be identified as an invoice, purchase order, shipping document number or similar unique identifier.
Prescription (Legend) Drug Pedigree DH 2129, 7/06 (obsoletes previous editions)

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BIOGRAPHICAL INFORMATION

LeNaiya Kydd was born in New York but has spent most of her life in Texas. LeNaiya is attending The University of Texas at Arlington as an Honors undergraduate student in the Biology Department. After receiving her Bachelors of Science degree, she plans on attending one of the medical schools in Texas in the Fall of 2016. LeNaiya desires to pursue a career as an anesthesiologist after completing medical school and to work in a hospital located in an underserved area to help provide care to people who would not normally be able to afford it. Her overall goal is to own her own practice in the future.