Impact of Drug Supply Chain Security Act on US Pharmaceutical Industry Under Decentralized Information Flow

by

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ABSTRACT

Drug counterfeiting is one of the major issues in the pharmaceutical industry across the world. These products could cause damages from ineffective treatments to death of patients. In order to fight against counterfeit drugs, the US government introduced Drug Supply Chain Security Act (DSCSA) mandating that all prescription drugs should be serialized. In addition, it mandates all pharmaceutical companies in the U.S. to provide tracking documents in response to a tracing request from FDA.

While the act aims to improve drug security across the pharmaceutical industry, it poses a huge impact across the supply chain on both physical flow and information flow. This research evaluates the supply chain impact at an industry level. In this thesis, we evaluate the supply chain impact of Matryoshka model and Unit level model supported by a decentralized information flow. The thesis then evaluates the supply chain impact from three aspects, operational cost, IT infrastructure cost and capital investment. We reference Nabiyeva and Wu’s research on centralized information flow model to conduct an exhaustive supply chain impact evaluation across the centralized model and the decentralized model. We conclude that among all these scenarios, unit level model under centralized information flow design bears the highest cost as it requires higher IT investment. On the other hand, the matryoshka model under decentralized information flow has a least supply chain impact from the cost perspective with low IT investment.

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1. **INTRODUCTION**

1.1. **BACKGROUND**

Drug quality is an important concern for pharmaceutical industries all over the world. The EU and countries such as India, China and Brazil have introduced laws to prevent counterfeit drugs. The U.S. passed the Drug Supply Chain Security Act (DSCSA) in 2013 to achieve the same result. The law mandates all the echelons to serialize medical product and provide the following documents on each serialized product when FDA request: Transaction Statement (TS), Transaction Information (TI), Transaction History (TH). This law impacts the entire US pharmaceutical industry and requires modification in business processes. The entire industry is looking for sustainable business models to achieve drug security by ensuring that counterfeit drugs do not enter the supply chain. Our thesis sponsors, GSK and CVS, are large players in the US pharmaceutical industry. They asked us to study the entire pharmaceutical supply chain and recommend business models which can be followed by the entire industry.

In order to recommend future business models, we studied the requirements mandated by the Drug Supply Chain Security Act (DSCSA). In addition to the law, we also studied the current state of the pharmaceutical distribution network. The as-is study would help us understand the processes within the pharmaceutical supply chain which would be affected by the DSCSA.

1.2. **DRUG SUPPLY CHAIN IN THE U.S AND IMPACT OF DSCSA**

(Rees, 2011) and (Whewell, 2009) have studied the US pharmaceutical industry and given a detail account of major echelons in the supply chain. They identify Manufacturers, Distributers, Pharmacies/Dispensers and Repackagers as four main echelons in the US pharmaceutical industry. We have studied the impact of DSCSA on all these echelons.

1. **Manufacturers:** Majority of the drug manufacturing is done by large pharmaceutical companies. These drug manufacturers are required to print the serial number on the lowest level of packaging. The serial numbers have to be unique and easily scanned for easy verification in the downstream.
2. Distributors: 80% of the drug sales in this echelon are done by 3 major companies – McKesson, Cardinal Health, and AmerisourceBergen. The distributors are required to verify at least 3 boxes or 10% of the volume, whichever is greater, when they receive products from manufacturers. They are expected to setup scanning systems and database systems to track and trace all products at the unit level.

3. Pharmacies/Dispensers: This is the echelon where the drugs are sold to consumers or patients. Ideally, the dispensers should be able to track the validity of every drug sold to the patients. Like the distributors, dispensers are expected to verify the validity of the products when they receive from distributors or manufacturers. A dispenser could be a large self-distributing dispenser (SDD) such as CVS or they can be a small store. A major bottleneck for the implementation would be in the small stores where a proper IT infrastructure is not present.

4. Repackagers: These companies buy products from the manufacturers or distributors and repackage or relabel products for easy use of patients. Repackagers are required to check the validity of the products they receive. Additionally, they are also required to print new serial numbers on the products they repackage or relabel like the manufacturers.

Based on (Rees, 2011), (Whewell, 2009), and our interviews with supply chain professionals in the pharmaceutical industry, we have identified the current state business processes. The process is mapped as a swim lane (figure 1) and it identifies the major processes of DSCSA on the pharmaceutical supply chain.
Figure 1: Current state physical and information flow in US pharmaceutical industry
1.3. Research Purpose

1. Explore different methodologies to implement serialization
2. From the whole industry perspective, provide a supply chain design that can minimize the overall impact across the value chain while enlarging the synergy across each echelon to develop a safer and more transparent supply chain.

1.4. Research Scope

As the law has a drastic impact all over the industry with a stretching timeline, the research needs to focus on the areas that have the most immediate effect. A scope is therefore defined for the thesis to ensure that it touch on all major aspects of the industry.

For the product, the thesis considers mainly all the medical products that required serialization except vaccine and cold chain product. As DSCSA only covers product sold in the United States, the research only covers US domestic market. In terms of the supply chain echelons, although all echelons are impacted by the law, DSCSA doesn’t mandate patient involvement. Therefore it isn’t included in the research. In addition, the repackagers are requested to serialized their product after the manufacturers and distributors. The model that manufacturers and distributors implement will largely influence repackagers so the thesis isn’t looking into detail with the repackagers. With all the echelons the research considers, it discusses the four major forward distribution models but it excludes the reverse logistics as that will mostly depends on the model built in the forward logistics model. Along with the possible solutions for physical flow, the research also touches on the alternatives of the data exchange models. While we discuss the different information flow designs that compliment the physical flow design, the thesis isn’t going to the technical detail of the IT implementation as the focus is more on the supply chain strategy level. The thesis further evaluates the solution design from operations, IT, and financial perspectives but it not planning to touch on product quality related area. The complete list of the research scope is listed in the following exhibit.
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2. LITERATURE REVIEW

The federal government has passed the DSCSA (Drug supply chain security act) in 2013. It mandated that all prescription drugs need to be serialized at a unit level and tracked throughout the supply chain. In order to implement serialization, a robust implementation methodology needs to be adopted across the supply chain.

The DSCSA contains deadlines for implementing Serialization in each echelon in supply chain i.e. Manufacturers, Distributers, Dispensers, and Re-packagers. It is mandatory for the companies to set up processes and systems which would enable verification of drugs. The systems and processes should enable the pharmaceutical supply chain to perform drug tracing, drug verification and drug identification in a seamless manner.

In this section, we discuss the details of DSCSA and various evaluation frameworks used to evaluate supply chains. A detailed understanding of the DSCSA will enable us to propose various implementation methodologies to implement serialization. The evaluation frameworks help us to evaluate the effectiveness of these implementation methodologies and compare them.

2.1. DRUG SUPPLY CHAIN SECURITY ACT (DSCSA)

The DSCSA, by itself, is very complex and touches on a wide variety of cases. The law touches on three key concepts – product tracing, verification, and identification – to achieve the end goal of supply chain security.

➤ Product Tracing:

“Beginning 1/1/2015, manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies beginning 7/1/2015) in the drug supply chain will provide information about a drug and who handled it each time it is sold in the U.S. market.”

Whenever ownership of a drug is transferred, with the exception of saleable returns, the company has to provide the following information to the company which receives the product:
1. Transaction Information (TI):
   - Proprietary or established name or names of the product;
   - Strength and dosage form of the product;
   - National Drug Code number of the product;
   - Container size;
   - Number of containers;
   - Lot number of the product;
   - Date of the transaction;
   - Date of the shipment, if more than 24 hours after the date of the transaction; and
   - Business name and address of the person from whom and to whom ownership is being transferred.

2. Transaction History (TH):
   A statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.

3. Transaction Statement (TS):
   A statement, in paper or electronic form, that entity transferring ownership in a transaction-
   - Is authorized as required under DSCSA;
   - Received the product from a person that is authorized as required under DSCSA;
   - Received transaction information and a transaction statement from the prior owner of the product, as required under the law;
   - Did not knowingly ship a suspect or illegitimate product;
   - Had systems and processes in place to comply with verification requirements under the law;
   - Did not knowingly provide false transaction information; and
• Did not knowingly alter the transaction history.

➤ **Product Verification:**

“No later than 1/1/2015, manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) shall establish systems and processes to be able to comply with the verification requirements.”

The verification process mandates that any player should be able to identify suspect products. A suspect product should be quarantined and an investigation needs to be conducted to determine if the product is illegitimate. The player should also be able to store all records for at least six years for a further review of FDA.

➤ **Product Identification:**

“No later than 4 years (11/27/2017), manufacturers, followed by repackagers (11/27/2018) shall place a unique product identifier on certain prescription drug packages”

The product identifier is a combination of National Drug Code/Serial number/Lot number/Expiration date. Wholesalers and Distributers should only trade products with identifiers.

The objective of the DSCSA is to enhance the security of Drug supply chain from illegitimate or counterfeit products. All players in the supply chain are responsible to verify the validity of the products and prevent counterfeit products from reaching patients.

2.2. AGGREGATION IN PRODUCT LABEL INFORMATION

To execute DSCSA, one important aspect is to determine how the structure of the product serialization data. Under current industry standards, in the shipping process, the product data is detailed at lot level at the label instead individual product level of either on the case or on the pallet. As the goods delivery to the customers, the shipping documents and labels is receive by customers at lot level. To execute DSCSA, mainly two models have been discussed by the industry. One straightforward method is to
have the serialization data on each individual product itself, which is referred as “unit level” model in this thesis. Another method, according to a report of Booz Allen Hamilton Consulting (2014), is to aggregate the product serialization data at either case level or pallet level, which is referred as “Matryoshka Model” in this thesis. The thesis is going to discuss the solution with both of these models and then evaluate the supply chain impact each incurs.

2.3. SUPPLY CHAIN PERFORMANCE EVALUATION

2.3.1. INTRODUCTION

Performance evaluation is a critical part in support supply chain decision making. A supply chain strategy has a wide range of impact on different areas in a company, including operations, business process, IT, finance, etc. To measure supply chain performance, we must first define the main performance goal from the supply chain perspective. Hausman mentions an established supply chain has to function on three dimensions: service, assets, speed. An outstanding supply chain provides services that help fulfill a customer’s demand with high quality and on-time. In addition, they hold healthy asset structure that balances inventory and cash (Hausman 2004).

To track whether a company achieves its supply chain performance goal, a comprehensive supply chain performance measurement system is required to effectively present the company status from different functionality across all level. A simple yet complete measurement based was introduced by Angappa Gunasekaran and Kobu (2007). A manager can structure the performance system from both quantitative and qualitative measurements. There are three challenges when a manager is structuring the system. First is to align the system with the company’s strategic goals. In addition, the performance system needs to be comprehensive to capture all the essential performance indicators. Most importantly, the manager needs to develop a solid measuring approach and implementation plan. To overcome these challenges, the authors propose eight main goals when designing a supply chain measurement system:

- Identifying success.
- Identifying if customer needs are met.
- Better understanding of processes.
- Identifying bottlenecks, waste, problems and improvement opportunities.
- Providing factual decisions.
- Enabling progress.
- Tracking progress.
- Facilitating a more open and transparent communication and co-operation.

(Angappa Gunasekaran & Kobu, 2007)

2.3.2. SUPPLY CHAIN PERFORMANCE MEASUREMENT FRAMEWORK

Various performance measurement frameworks can be used to evaluate supply chains. Among all the frameworks, Gunasekaran, Patel, and McGaughey proposed a two-dimensional framework that classifies performance measurements based on supply chain activities and functionality level. For functional axis, the framework define a three-level hierarchy: strategic, operational, and tactical. For supply chain activities, the framework present for categories: plan, source, make, and deliver. Based on these two axes, the article discusses these performance identifiers:

Order Planning: including order entry method, order lead-time, customer order path

Evaluation of Supply Link: including evaluation of supply link, strategic level measures, tactical measures, operational measures

Production: including range of product and service, capacity utilization, effectiveness of scheduling techniques

Delivery: including number of faultless notes invoiced, flexibility of delivery systems to meet particular needs, distribution cost
Customer service and satisfaction: including flexibility, customer query time, post transaction measure of customer

Supply chain and logistics cost: including cost associated with assets and return on investment, information processing cost.

(Gunasekaran, Patel, & McGaughey, 2004)

Angappa Gunasekaran and Kobu also propose a similar two dimension framework that applies to supply chain activities in one axis. However, instead of using functionality level, the authors use financial and non-financial indicators to categories the measurement. For financial indicators, the matrixes focus more on the return on investment, operations cost, and value added. For non-financial indicators, the matrixes mostly measure time related performance, operation efficiency, and supply chain flexibility. (Angappa Gunasekaran & Kobu, 2007)

Some researchers incorporate other business evaluation methods into supply chain performance measurement. For example, Bhagwat and Sharma apply the balance scorecard concept and create four perspectives for a supply chain focused balance scorecard, which are finance, customer, internal business process, and learning and growth (Bhagwat and Sharma 2007).

2.3.3. CONCLUSION

By understanding various effective supply chain performance measurement frameworks and the high priority indicators in these frameworks, we can design an evaluation structure to measure all the potential solutions for serialization in the supply chain. This evaluation will determine which solution is most suitable for the pharmaceutical industry in the evaluation section.

In this thesis, we consider a few KPIs to evaluate the impact of DSCSA on the pharmaceutical supply chain. First, we compare the impact of turnaround time and inventory turns for the entire supply chain. This impact is explained in more detail in the Impact Evaluation and Implication section. Then we evaluate the one-time investment cost on machinery (CAPEX) and IT infrastructure. Finally, we also evaluate the recurring cost to maintain the IT infrastructure so that the processes can be sustained.
To compare the various implementation methodologies, we calculate the net present value of the cost based on a ten-year horizon. These costs are compared for the various models.
3. **Methodology**

The U.S. federal government passed the DSCSA (Drug supply chain security act) in 2013. It mandated that all prescription drugs need to be serialized at a unit level and tracked throughout the supply chain. In order to implement serialization, a robust implementation methodology needs to be adopted across the supply chain.

The DSCSA contains deadlines for implementing Serialization in each echelon in supply chain i.e. Manufacturers, Distributers, Dispensers, and Re-packagers. It is mandatory for the companies to set up processes and systems which would enable verification of drug. The systems and processes should enable the pharmaceutical supply chain to perform drug tracing, drug verification and drug identification in a seamless manner.

In this chapter, we discuss the various physical processes and IT architecture that the industry could use. We also evaluate the impact on key KPIs such as operational cost and investment for all the implementation methodologies in the impact evaluation section.

3.1. **Implementation Methodology**:

We studied the as-is business processes within the pharmaceutical supply chain through research and interviews with key stakeholders. Based on this study and the requirements mandated by the DSCSA, we came up multiple business processes that could be implemented post serialization. These business processes contain two main parts: the physical flow of product and information flow of serial number information.

We identified two possible implementation methodologies for both the key variables. The information flow from one echelon to another could be either centralized or decentralized. In the centralized information flow model, all the transactional information is uploaded to a central database. All players in the supply chain read information from the central database. This database could be owned by manufacturers or FDA or third party service providers. In the decentralized information flow model, all transactional information is passed from one echelon to the other. The data is not stored in a central
database. The upstream echelon would pass only the serial number information of the products shipped to the downstream echelon. Thus, different organizations would create informational flow links with each other based on business requirement. The information flow can be electronic or on paper.

The physical flow process could be based on a Matryoshka model or at a unit level. In the Matryoshka model, there exists an aggregation of units to cases and cases to pallets. Figure 2 depicts the Matryoshka model. A case, which contains many units of drug, has a serial number label on it. The data is stored in such a way that if the case label is scanned, anybody in the supply chain who has the information flow from upstream can retrieve unit level information. Hence, all the serial number related information of the products within the case can be retrieved. Similarly, a pallet has a serial number label on it. This label is mapped to all the cases serial numbers within the pallet. This makes information retrieval and verification process simple.

![Figure 2: Matryoshka Model](image)

In contrast, the physical flow processes can be based on a unit level model. In this model there is no label on cases or pallets which links to all serial numbers of products stored within them. During the verification process, pallets and cases have to be broken down at a unit level and verification is possible only at the unit level.

Thus, based on the information flow and physical flow model we identified four different implementation methodologies post serialization. The model scenarios are as follows:

1. Centralized information flow with “Matryoshka” nesting of data
2. Decentralized information flow with "Matryoshka" nesting of data

3. Centralized information flow with unit level data, no nesting

4. Decentralized information flow with unit level data, no nesting

In this thesis, we will deep dive into the business process and analyze the impact of the decentralized information flow models. The centralized information flow models is analyzed in detail in thesis written by Nabiyeva & Wu, 2017

3.1.1. DECENTRALIZED INFORMATION FLOW WITH "MATRYOSHKA" NESTING OF DATA

In this model, the TI/TH/TS is passed on from one echelon to another. The serial number and related information are stored in internal databases owned by each organization. When a shipment is sent downstream, the relevant serial level info for only the products shipped is also sent downstream. The overall process in a four echelon supply chain is depicted in figure 3. The process considers four different echelons:

a. Manufacturers: In this process, the manufacturers produce the product with serial numbers printed on each unit. When these units are packaged in cases and pallets, the manufacturers print labels on cases/pallets. The pallets → cases → units mapping is stored in a database which is owned by the manufacturer. These pallets are stored for future shipments. When the manufacturers receive sales orders from downstream, they pick the products based on the volume requirement and ship the products downstream. Along with the physical products, they also send the serial number information in a nested manner or in a Matryoshka model to the downstream receiver.

b. Wholesaler: When the wholesaler receives a shipment, they also receive the serial number information electronically or on a piece of paper. The wholesaler has to verify the physical products with the serial number information. The reconciliation process will be dealt in more detail when we discuss the inbound receipt process. If the products are verified, the wholesalers store the products for shipments in future. When they receive sales orders from downstream, they follow the same process as manufacturers for shipment to downstream.
Figure 3: Decentralized model with Matryoshka
c. Dispensers: The dispensers are expected to do the verification process similar to the wholesalers. If the dispenser has retail stores owned by them, then they can ship to the retail stores without sending the associated serial number information because there is no transfer of ownership of the drug. This drug can now be dispensed to the consumers based on prescriptions.

Once serialization is implemented in the pharmaceutical supply chain, there are two key processes which will be impacted the most. They are the outbound shipment process and inbound receipt process. These two processes will have a huge impact on the turn-around time and the operating cost post serialization.

3.1.2. DECENTRALIZED INFORMATION FLOW WITH UNIT LEVEL DATA, NO NESTING

The overall process in a four-echelon supply chain is depicted in figure 3. The overall process is very similar to the one described above for Matryoshka model. The key difference between the two models is that there is no nesting of serial information from units to cases or pallets. The cases do not have a label on them and they cannot be mapped to individual units within each case. Similarly, a pallet has no label and they cannot be mapped to the cases within the pallet. The serial information is stored only at a unit level within the organization. This information is passed from one echelon to another based on the products that are shipped from one echelon to another.
Decentralized information flow with unit level model

Figure 4: Decentralized model with Matryoshka
3.2. OUTBOUND SHIPMENT PROCESS FOR DECENTRALIZED INFORMATION FLOW MODEL

3.2.1. MATRYOSHKA MODEL

In this process, the pallets are stored in any echelon of the supply chain with a pallet/case label on them. These labels help us track the serial numbers of the units contained in pallet/case. Once the sales order is received the pallets are picked as full pallets if the volume is high. If the volume is low, then the pallets are broken and cases are picked to satisfy the order. The full pallets’ label is scanned and the list of all serial numbers in the pallet is tracked. The cases are scanned and consolidated into a mixed pallet. A new label number is created for the mixed pallet and a new nested data structure is created for the mixed pallet. The label is printed on the mixed pallet.

All full pallets and mixed pallets are consolidated into the shipment and, in parallel, all the serial number information are consolidated and mapped to the shipment. Once the shipment is loaded and sent to the customer, the serial level information is also sent to the customer electronically in a nested format.

![Figure 5: Outbound shipment process – Matryoshka](image)

3.2.2. UNIT LEVEL MODEL

In this process, the serial numbers are only present at the lowest unit level. There are no labels on pallets/cases which contain multiple units of the same drug. Once the sales order is received, full pallets are picked if the volume is high. If the volume is low, then the pallets are broken and cases/eaches are picked. The full pallets and the cases are broken down on a unit level and all units are scanned for the
serial numbers. Once all units are scanned, the pallets and cases are reconstructed and shipment is consolidated. In parallel, all the serial number information within the shipment is consolidated and mapped to the shipment number.

Once the shipment is loaded and sent to the customer, the serial level information is stored internally and also sent to the customer electronically on a unit level.

3.3. INBOUND RECEIPT PROCESS FOR DECENTRALIZED INFORMATION FLOW MODEL

3.3.1. MATRYOSHKA MODEL

In the downstream supply chain echelon, the physical shipment is received along with the serial number information for all the units in the shipment in a Matryoshka format. The full pallets and the mixed pallets are verified based on the information provided by the supplier and scanning the products. If the serial information matches and the product seem legitimate, the products are stored in the warehouse. If the serial information does not match or the product is suspected to be illegitimate, then the product is quarantined. As per the DSCSA, once the product is quarantined a prompt investigation is carried out upstream. The upstream supply chain players have to respond to inquiries made and prove that the product is legitimate. If the receiver deems the product as verified
after the upstream players prove its legitimacy, the product is placed in storage. Else, FDA needs to be notified regarding the suspected product.

\[\text{Figure 7: Outbound shipment process – Matryoshka}\]

3.3.2. Unit Level Model

In the downstream supply chain echelon, the physical shipment is received along with the serial number information for all the units in the shipment at a unit level. The pallets have to be broken down and individual units are scanned. The units are verified with the serial number information given from the supplier. If the serial information matches and the product seem legitimate, the products are palletized and stored in the warehouse. If the serial information does not match or the product is suspected to be illegitimate, then the product is quarantined. As per the DSCSA, once the product is quarantined a prompt investigation is carried out upstream. The upstream supply chain players have to respond to inquiries made and prove that the product is legitimate. If the receiver deems the product as verified after the upstream players prove its legitimacy, the product is palletized and placed in storage. Else, FDA needs to be notified regarding the suspected product. The key difference between the Matryoshka model and the unit level model is in the level at which activities are done. In the Matryoshka all the activities are done at the highest working level of unit of measure that could be a pallet, case or unit. In
contrast, all the activities in the unit level model are done in the lowest level of unit of measure that is a unit.

![Diagram of Outbound Shipment Process – Unit Level](image)

*Figure 8: Outbound shipment process – Unit Level*

In the evaluation section, we will quantify the impact of the processes explained above. The impact on turnaround time will be quantified based on the estimate of volume going through any process and time taken for each step. The impact on operating cost will be quantified based on the estimate of volume going through any process and cost for each step. These impacts will help us compare all the four possible implementation methodologies. Along with turnaround time and operating cost, qualitative factors such as process reliability and implementation ease will also be considered while determining the optimal methodology.

### 3.4 Future Data Exchange Model: Decentralized Structure

To comply with FDA tracking requests, smooth data exchange across all echelons is critical. There are mainly two models being considered, centralized model and decentralized model. The major difference between these models is if the data is hosted by each echelon separately or consolidated in one central database. This research focuses on discussing decentralized data exchange model in coordination with the physical flows mentioned in the previous section.
The decentralized data exchange model we discuss is based on several assumptions. First, we assume that major manufacturers, wholesalers, self-distributed dispensers and some high-volume dispensers would develop data connections to communicate between themselves. For independent pharmacies and dispensers, we assume that portal systems will be provided by upstream echelons as they will not have their own IT capability to build electronic data exchange mechanisms. Lastly, we assume that self-distributing dispensers are not required to send TS/TI/TH data when shipping from the distribution center to their pharmacies as the movement remains in the same legal entity.

Based on these assumptions, the data of each serialized product is stored in each echelon. When a shipment happens, the TS/TI/TH data of the specific shipment will be sent to the customer. The receiving company will need to store the incoming data and further generate outgoing TS/TI/TH when shipping out products to downstream customers. This is the general practice across manufacturers, distributors, and self-distributed dispensers. Independent pharmacies and dispensers will need to log in to a portal system retrieving TS/TI/TH data when receiving an incoming shipment. The data will be used to validate the serialization information on the physical products.

When the FDA files a tracing request for a certain serial number, all players search their own database to find the corresponding TS/TI/TH data with the information of the supplier one step upstream. The FDA then needs to piece all the information they receive together to have the end-to-end shipping history from the dispenser to the manufacturer.
Figure 9: Data exchange model - decentralized
4. IMPACT EVALUATION & IMPLICATIONS

In this chapter, we will evaluate the impact of the changes in processes mandated by the requirement of serialization in the US pharmaceutical supply chain. We develop an impact evaluation method to capture the supply chain impact of executing DSCSA from operations lead time and IT investment, and then incorporate with a cost evaluation model developed by Nabiyeva and Wu.

4.1. OPERATIONS IMPACT EVALUATION

The operations impact across various implementation methodologies can be evaluated by understanding the effect of each step in the outbound shipment process and the inbound receipt process. Once serialization is implemented, the process steps would have different time requirements. Once we identify the time requirements for each step, we can roll it back to a whole supply chain level. The supply chain impact can be evaluated by aggregating the time required for each step across all the volume that flows through each process step.

Based on our interviews with key supply chain stakeholders in the U.S. Pharmaceutical industry we understand the impact of serialization on the processes. In the Matryoshka model, the serial number information is aggregated on the cases and pallet. Thus, it is enough for warehouse employees to scan the label at the case or pallet level to get serial number information for all units. Whereas in the unit level model, it will be more cumbersome for all players in the supply chain to scan each unit to verify products.

In our model we only consider 3 echelons – Manufacturer, Distributor, and Dispenser. But the actual pharmaceutical supply chain is more complex. In cases like CVS and Walgreens, the supply chain only has two echelons. Whereas in cases of small dispensers, the supply chain could contain many more echelons. On an average, for all prescription drugs in U.S. the number of echelons is three and thus we evaluate the impact on a three echelon model.

In order to evaluate the impact of Matryoshka model vs unit level model, we need to understand the total process time at each echelon. It is necessary to understand the split of the total volume flowing out
of each echelon as pallets vs cases vs totes (units). Based on our interviews we assumed the following split of volumes.

<table>
<thead>
<tr>
<th>Echelon</th>
<th>Pallets</th>
<th>Cases</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>60%</td>
<td>35%</td>
<td>5%</td>
</tr>
<tr>
<td>Distributor</td>
<td>1%</td>
<td>2%</td>
<td>97%</td>
</tr>
</tbody>
</table>

*Table 1: Volume splits by handling UOM*

### 4.2 IT Investment Evaluation Framework

In addition to the impact on physical flow, the information flow throughout the whole value chain also requires a lot of changes. To evaluate the impact, we developed a framework to capture the IT investment required to execute the change. The framework is based on the assumption that the data generated from manufacturers, distributors, and self-distributed dispensers are hosted in-house. In addition, the distributors need to provide portal systems for independent pharmacies and dispensers. Furthermore, as each company has very diverse plans for building server room/farm, the construction cost is not considered in this framework be maintain a comparison baseline.

The core concept of the framework is to first estimate the average IT investment for one company for each echelon, and then multiply by the number of players to get the industry total. For wholesalers, based on the size difference in each echelon, the framework includes a weighted factor to reflect the different scale of investment companies of different size might face. For independent dispensers, considering most small businesses don't have the capacity to build their own IT systems, the framework assumes a very small percentage of the dispensers would invest in IT related project.
The cost is categorized into initial investment and annual recurring cost. Initial investment includes the one-time upfront investment required to execute serialized data exchange, and the recurring cost covers the annual maintenance fee to continue hosting the data exchange model.

The first cost element in the initial investment category is data storage. To estimate the data storage cost, we determine the required data storage volume. We first determine the annual receiving and shipping quantity to calculate the annual transaction volume. Then we multiply this with eight, the number of years the companies have to store data for. With the understanding of the average server space cost, we multiply the annual data volume with average server cost to get the overall server cost. After considering additional investment in network device and service to secure the transmit bandwidth and other necessary infrastructure construction cost, we can calculate the expected data storage cost.

The second cost element is the interface development cost. In the decentralized model, different interfaces need to be developed to accommodate different IT structures and existing electronic data interfaces (EDI). We assume that all big companies have to develop data exchange connections with players in the upstream and downstream echelons to remain competitive. In order to capture the potential impact, we determine the total number of interfaces needed. This number is calculated as the number of direct business distribution partners, including upstream suppliers and downstream customers, times the number of the interface need to develop for each partner. Although, there might be a different number of the interface needs to be built for different partnerships. We assume that a basic set of interfaces that can fulfill the fundamental requirement of sending TS/TI/TH data and responding to FDA tracing request. We can estimate the total development cost by multiplying the number of interfaces with the average cost for developing an interface.

![Table: Manufacturer, Wholesaler, SSD](image)

**Figure 10: IT investment - data storage framework**

The second cost element is the interface development cost. In the decentralized model, different interfaces need to be developed to accommodate different IT structures and existing electronic data interfaces (EDI). We assume that all big companies have to develop data exchange connections with players in the upstream and downstream echelons to remain competitive. In order to capture the potential impact, we determine the total number of interfaces needed. This number is calculated as the number of direct business distribution partners, including upstream suppliers and downstream customers, times the number of the interface need to develop for each partner. Although, there might be a different number of the interface needs to be built for different partnerships. We assume that a basic set of interfaces that can fulfill the fundamental requirement of sending TS/TI/TH data and responding to FDA tracing request. We can estimate the total development cost by multiplying the number of interfaces with the average cost for developing an interface.
The last cost element is related to internal system adjustment. In addition to developing new systems, existing IT systems have to be revamped to be compatible with newly developed interfaces and changes in physical flows. We identify the most affected functions along with the corresponding IT systems that require change. We then estimate the required man-days to finish the change and multiply by average labor cost per man-hour to determine the overall system adjustment cost.

In addition to the initial investment cost, another category of cost is the recurring cost. This cost is incurred because the IT infrastructure requires continuous maintenance to ensure that it operates smoothly. For manufacturers, distributors, and self-distributed dispensers, the main recurring cost lies in storage maintenance and interface maintenance. Additional manpower is required to maintain the data exchange service. In this framework, the cost is determined by additional human resource needed times the annual salary. On the other hand, there’s no extra maintenance needed for independent pharmacies and dispensers as they use the portal systems provided by upstream echelons. However, we expect there is an annual charge for using the portal system as the upstream echelons bear all the investment for building the portal systems.

With the understanding in operations and IT, we leverage the framework that Nabiyeva and Wu (2017) developed to evaluate capital expenditure (CAPEX). Then we compare all implementation methodologies based on operating cost, IT cost and CAPEX. This framework provides a full view of the financial impact of executing DSCSA.
5. COMPARATIVE ANALYSIS AND CONCLUSION

The evaluation framework is developed not only to evaluate the supply chain impact decentralized structure but also to compare the impact of centralized and decentralized models. And also to understand the different pros and cons. In this section, we will summarize the comparative analysis on financials.

5.1. OPERATIONS IMPACT

The difference between Matryoshka model and unit level model in the inbound receipt process of the distributors is significant at the distributor. As described in the table before, the manufacturers send a significant portion of volume downstream to the distributors in pallets or cases. In the Matryoshka model, the distributor has to only scan the cases or pallets to verify all serial numbers within the pallet. In the unit level model, the distributor has to scan all the inbound volume at the unit level. This would be a very time-consuming process and would bring the entire supply chain to a standstill. Thus, the distributors and dispensers would only verify a sample from the total volume. DSCSA mandates that this volume has to be three packages (cases) or 10% of volume, whichever is higher. Thus, the distributors will only verify serial number information of only 10% of the inbound volume.

Even though the distributors will only verify 10% of the volume, the unit level verification process would be more time-consuming than verification through Matryoshka model. We calculated the inbound receipt time based on the splits mentioned in table 1 and the process times identified through interviews. The inbound receipt process time at the dispenser level does not change much because the volume flow is majorly in totes (unit). The verification process would be similar between unit level model and matryoshka model. However, the inbound receipt process at the distributor would be 50% longer in the unit level model compared to the matryoshka model.

The outbound shipment process at the manufacturer would be significantly longer at the manufacturer. This is primarily because the manufacturer cannot sample only 10% of the volume. The manufacturer has to scan all products at the unit level before sending it downstream in order to send the appropriate serial number information along with the shipment.
We calculated the outbound shipment time based on the splits mentioned in table 1 and the process times identified through interviews. The outbound shipment process time at the distributer level does not change much because the volume flow is majorly in totes (unit). The process would be similar between unit level model and matryoshka model. But, the outbound shipment process at the manufacturer would be 500% longer in the unit level model compared to the matryoshka model as shown in figure 13.

**Figure 12:** Inbound receipt process comparison at a distributor

**Figure 13:** Outbound shipment process comparison at a manufacturer
5.2. IT INVESTMENT

To compare between the IT investment in the centralized model and decentralized model, we use a similar estimation assumption. The assumption is regarding how we calculate annual handling quantity for each echelon. In our analysis, we use annual prescription quantity along with the average number of pills per prescription to estimate the number of pills produced/consumed annually.

We first look at the company level for each echelon. Under the decentralized model, the analysis shows that there's an even amount of initial investment needed for all echelons except for dispensers. The wholesalers need to invest a slightly higher upfront cost among all echelons as they need to handle both incoming and outgoing information. In terms of recurring cost, manufacturers, wholesalers, and self-distributed dispensers only require a small amount of cost for in extra manpower to maintain the service. On the other hand, dispensers need to pay an expected high annual service fee to use the portal system provided by upstream echelons.

Under the centralized model, the cost structure is different. According to Nabiyeva and Wu (2017), the initial investment is higher for the echelon that is responsible for building the centralized storage system. The manufacturer is one potential candidate echelon as they can benefit the most with information on end consumption. Although, wholesalers and distributors will resist this as they will lose their competitiveness as manufacturers will have complete visibility downstream. Another alternative is to have a third-party vendor hosting the centralized system for the whole industry, and the companies pay a service fee in return. The initial investment of all the other echelons is relatively small. However, when it comes to annual incurring cost, all the other echelons are required to pay a high service fee to use the centralized data system to share the initial investment. The third alternative is for the federal government to build and maintain the central database. These centralized alternatives improve the efficiency of tracking and tracing drugs. It is also easier to build a predictive algorithm for detecting counterfeit drugs before it reaches patients on a central database. But, it is would be a very costly and resource intensive undertaking for the federal government. The manufacturers can possibly afford to build such a database. In addition, there could be significant supply chain benefits for the manufacturers.
from the downstream supply chain visibility. But, the downstream players’ business data privacy would be at risk.

In the echelon level, the thesis compares the cost from the echelon as the whole to the level of impact for each player in the industry supply chain. The analysis shows that implementing the decentralized model poses a higher upfront investment for manufacturers and self-distributed dispensers as there are more players in these two segments. Some part of the cost is then transferred to dispensers when they pay the annual portal system service fee. On the other hand, most of the initial investment lies in the manufacturers to build the centralized system. For other echelons, the cost incurs annually when using the centralized data service.

Finally, we consolidate all the investment to look the industry level. As a whole, the decentralized model as a lower cost compared to centralized model if the centralized system is hosted by manufacturers. It implies that decentralized model can leverage more on the capacity in each company and requires less investment to set up the serialized data exchange model. The difference is even larger when we further construct an NPV analysis for the recurring cost. We found that centralized method creates a higher NPV in cost for all echelons.

5.3. **FINANCIAL IMPACT**

There are four different implementation methodologies being compared:

1. Centralized information flow with “Matryoshka” nesting of data
2. Decentralized information flow with “Matryoshka” nesting of data
3. Centralized information flow with unit level data, no nesting
4. Decentralized information flow with unit level data, no nesting

For the first scenario, wholesalers, self-distributed dispensers, and dispensers have a low financial impact as there are no significant changes in the inbound receiving process. The required equipment and investment for these echelons are mainly for picking and packing process. However, a higher cost
required for manufacturers to develop the centralized portal system and to aggregate shipping data in Matryoshka model.

In terms of decentralized data exchange model with Matryoshka physical flow model, the financial burden lies evenly across the industry supply chain. Each echelon needs to build their own data storage solution along with the interface with other companies to transfer the TS/TI/TH information. To implement the Matryoshka model, the manufacturers also need extra investment to aggregate the data to pallet level. Once the data is aggregated, there’s only limit investment needed for the downstream echelons.

For centralized data exchange with unit level model, there is a moderate investment for wholesalers, self-distributed dispensers, and dispensers. This is because it requires extra workforce and equipment investment to break down the pallets and case for unit level good receiving process. A significant investment for manufacturers is still needed to build centralized data storage system.

The last model, decentralized data exchange model with unit level physical flow model, has an uneven investment spread among the supply chain echelons. This model required a high-level investment for wholesalers and self-distributed dispensers as they not only need to develop data storage solutions, but also need an extra workforce to support the unit level good receiving process in the distribution centers. The manufacturers bear a mid-level financial impact as they don’t need to aggregate the data when sending TS/TI/TH information to downstream echelons. There’s only a limited amount of investment required for the dispensers, which is mainly in the service fee for using portal systems provided by upstream echelons.

5.4. OVERALL EVALUATION

Nabiyeva and Wu (2017) discuss more on the centralized models and we compared the cost impact of decentralized model with these centralized models. The centralized database can be owned by manufacturer or a third party service provider or the federal government. The thesis compares all the
models based on a ten-year evaluation of the costs. The costs could be a one-time investment or an annual recurring cost.

The costs considered are operating cost, IT cost and capital expenditure (CAPEX). These costs are aggregated over all the echelons of the pharmaceutical supply chain to compare the overall impact. The recurring costs are discounted at a rate of 10% to calculate the net present cost.

<table>
<thead>
<tr>
<th>Data model</th>
<th>Physical model</th>
<th>IT Investment</th>
<th>Operating Cost</th>
<th>CAPEX</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>One time Investment</td>
<td>Net Present Cost - 10 Year Recurring</td>
<td>Net Present Cost - 10 Year Recurring</td>
</tr>
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<td>Centralized (3rd party)</td>
<td>Matryoshka</td>
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<td>13.7c</td>
<td>1.0f</td>
</tr>
<tr>
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<td>Unit Level</td>
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<td>1.2f</td>
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<td>1.2f</td>
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</tr>
<tr>
<td>Decentralized</td>
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<td>1.0c</td>
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<tr>
<td>Decentralized</td>
<td>Unit Level</td>
<td>1.0a</td>
<td>1.0c</td>
<td>1.2f</td>
</tr>
</tbody>
</table>

Table 2: Relative comparison of costs by cost head

Table 2 gives the relative costs of each cost head compared to different implementation models. We use Decentralized Matryoshka model as the baseline model for comparison. When we compare the one time investment for IT, it is costlier for centralized data model owned by manufacturers as the number of manufacturers are more in numbers. In addition, all of them have to build data pipelines to all echelons in the supply chain. This would be relatively higher investment.

Discounted recurring cost for IT would be highest for Govt. or 3rd party model because most of the cost will be charged as annual recurring cost. The discounted recurring operating cost for Matryoshka model would be lower than Unit level model because of shorter process times for inbound and outbound processes.

Finally, the CAPEX is lower for unit level model as there will be lesser packaging requirements. For Matryoshka model, the packaging lines have modified and more labelers have to be installed to enable serialized labeling at different UOMs.
Table 3: Cost Comparison Summary

Table 3 shows the comparison of costs of all the implementation methodologies on a relative basis. We use the On-time IT investment for centralized (third party) Matryoshka model as the baseline. Our research shows that among all the alternatives implementing centralized model, using third party vendor for data system to implement a unit level physical flow inures the highest cost as the recurring cost in operations and IT investment add up over time and eventually reflect on a long range NPV analysis. In addition, by implementing unit level model in physical flow, the lead time increase tremendously as each pallet needs to be broken down when shipping/receiving the goods. On the other hand, the centralized data exchange model hosted by manufacturers with the Matryoshka physical flow model has less recurring cost over time as the IT investment is evened out by the benefit of lower operations cost.

For decentralized models, the impact is slightly lower when implementing Matryoshka model in the physical flow. By aggregating TS/TL/TH data to pallet level, operations impact is contained as it doesn’t require longer time to break down incoming shipment. Under the decentralized model, each company can build their own data storage solution that suits its current IT environment and therefore the impact is minimized. These advantage transfer into less financial impact across the value chain. However, on the other hand, when implementing a unit level model in physical flow, it again creates higher impact in operational cost. Transferring unit-level data requires pallet breakdown in inbound receiving for each echelon, and creates the need for the additional workforce. Eventually, it creates more financial impact as a higher investment is required to support the model.
Figure 14 shows the comparative analysis of cost incurred for the next ten years. The lowest cost option is decentralized model. The decentralized model cannot be used efficiently for predictive counterfeit drug detection. The FDA has to raise a request in order for companies to provide information on transactions. Then these transactions across various echelons need to be strung together separately and the discrepancies have to be identified.

All players in the supply chain require their data to be private in order to be competitive. A centralized model would be most efficient for counterfeit drug detection. However, a centralized model could be used by players within the supply chain to get rid of their competitors or remove different echelons in the supply chain. This could potentially further increase the margins for big players. On the other hand, decentralized model ensures business privacy and data security for individual players in the supply chain.

![Cost (10 Years)]

*Figure 14: Comparison of cost across all implementation methodologies*

5.5. INDUSTRY REALITY
The reality in the pharmaceutical industry is that the supply chain is more complex than what is assumed in the models. There are many players in the supply chain in each echelon of the supply chain. In the manufacturing space, there are multiple large players and a long tail of small manufacturers. Among these manufacturers, there are traditional manufacturers whose profit margins are high and there are generic drug manufacturers whose margins are low.

Some of the manufacturers, especially small and generic drug manufacturers, will not have enough investment for developing the matryoshka model. They might take higher operational cost due to longer lead times on an annual basis rather than investing upfront on packaging equipment.

As a result, the pharmaceutical supply chain would adopt a mix of unit level model and matryoshka model. This would lead to more complexity with operations downstream especially when there are mixed pallets with part matryoshka and part unit level. It would be difficult for supply chain players to standardize their business processes.

5.6. LIMITATIONS & TOPICS FOR FUTURE RESEARCH

5.6.1. REPACKAGER

Repackagers are companies that buy pharmaceutical products from manufacturers or distributors. They break the packages and put the drug into new package types. The packages could be smaller quantity units or even unit dose packs. The repackagers are not allowed to modify the drug itself in any way or change the dosage.

According to the DSCSA (Drug Supply Chain Security Act), the repackagers act as both distributors and manufacturers. Thus, they have to verify the products when they receive from upstream. In addition, they also have to serialize the new packages like manufacturers in accordance with the mandate.

The complexity with supply chain visibility increases with repackagers because:

1. Physically the number of units increase significantly.

2. Mapping the inbound serial numbers with the outbound serial numbers would be extremely
difficult.

In this thesis we do not quantify the impact on repackagers. The DSCSA’s impact on repackagers is more complex than on manufacturers and distributors. But the impact in the process would be similar to manufacturers and distributors as discussed the implementation methodology section.

5.6.2. NEW TECHNOLOGY APPLICATION: CLOUD SERVICE, RFID

The discussion of this thesis is based on leveraging the widely used technology by the industry currently to provide a practical view and solution that can be quickly implemented. However, there are several emerging technology can be considered to further improve the efficiency for executing DSCSA.

The first technology is regarding RFID. Traditional labels require a manual process to scan the label, thus creating the burden of breaking down pallets and cases to retrieve the information. RFID technology enables a smart label to be detected when passing through specific equipment without scanning action. Applying this technology to the implementation of DSCSA, it’s possible to retrieve the serialization data without breaking down any cases. The technology can potentially solve the problem of deciding whether aggregate the data or not. In addition, we can imagine this technology improving the inbound receiving efficiency as there’s no need to separate the data validation and physical good validation as it can performing data matching with incoming electronic data as well.

Another technology can be further discussed in the cloud technology. Traditionally, companies build its in-house server room or data center to store business data. With more cloud service providers emerging, they create alternatives for the pharmaceutical industry to store serialization data. With the cloud service, there’s no upfront capital investment needed for the companies as the cloud service providers handle all the infrastructure construction and charge their customers with a service fee. In addition, the service fee is charged based on the storage space that the business data occupies, which means it provides a flexibility for the company to easily scale up or down. Furthermore, with the economy of scale, these cloud service providers have the capability to invest a lot more in data security and contingency planning, therefore provide professional services that have higher data security level at a lower spending. Through the process of the research, we believe the serialization data volume is
growing fast with uncertain volatility. In addition, a high level of data security is required to avoid the
data is easily access by counterfeiters. With this requirement, cloud service can be considered as a
valuable alternative. More research in the field is required to discuss how to apply cloud service in the
information flow throughout the industry supply chain.

5.6.3. CONTINUE FIGHTING COUNTERFEIT DRUGS

The intention of DSCSA is to strengthen the security of the medical product and increase visibility
across the US pharmaceutical supply chain. As we can foresee the law will effectively trace the source
of a questionable product and finding the potential counterfeiters in the supply chain, there are still
many improvements to be made to create a more secure drug supply chain that could eliminate
counterfeit drug flowing into the end patients.

This research provides a high-level evaluation on major alternatives to implement DSCSA for the
industry supply chain. In the future, we are looking forward to conduct more research in this area, not
only focusing on complying with the law, but also leveraging the data exchanges across the industry.
In addition, we need to recommend operational changes to provide better efficiency across the supply
chain and a reliable process to fight counterfeit drug in every step.

5.7. CONCLUSION

In this thesis, we identified the impact of various implementation methodologies on the U.S.
pharmaceutical supply chain. This study identifies the key changes in supply chain processes and the
IT infrastructure required to support serialization. We also discuss the qualitative pros and cons of
various methodologies. Based on the thesis, pharmaceutical players can now take an informed decision
on which implementation methodology to adopt. It would help the U.S. pharmaceutical industry to
standardize their supply chain as much as possible. Pharmaceutical supply chain efficiency would be
higher with more standard processes.
BIBLIOGRAPHY


Drug Supply Chain Security Act (2013)


