Drug Serialization Impacts Under Decentralized Data Management

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Summary: Drug counterfeiting is one of the major issues in the pharmaceutical industry across the world. 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. The thesis then evaluates the supply chain impact from three aspects, operational cost, IT infrastructure cost and capital investment. 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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KEY INSIGHTS

1. Matryoshka model has better operating efficiency than unit level serialization model.
2. Centralized information flow with unit level serialization is much costlier than decentralized information flow with matryoshka model.
3. Centralized information flow has more flexibility for building predictive algorithms

Introduction

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.

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. Distributers: 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.

Methodology

We identified two possible implementation methodologies for information flow and physical flow. 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 1 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 1: Matryoshka Model

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

- Centralized information flow with “Matryoshka” nesting of data
- Decentralized information flow with “Matryoshka” nesting of data
- Centralized information flow with unit level data, no nesting
- Decentralized information flow with unit level data, no nesting

Comparative analysis

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 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.

Data model	Physical model	IT Investment		Operating Cost	CAPEX
		One time Investment	Net Present Cost - 10 Year Recurring	Net Present Cost - 10 Year Recurring	One time Investment
Centralized (3rd party)	Matryoshka	0.1a	13.7c	1.0f	1.0i
Centralized (3rd party)	Unit Level	0.1a	13.7c	1.2f	0.6i
Centralized (Manuf)	Matryoshka	1.9a	5.8c	1.0f	1.0i
Centralized (Manuf)	Unit Level	1.9a	5.8c	1.2f	0.6i
Centralized (Govt.)	Matryoshka	0.1a	13.6c	1.0f	1.0i
Centralized (Govt.)	Unit Level	0.1a	13.6c	1.2f	0.6i
Decentralized	Matryoshka	1.0a	1.0c	1.0f	1.0i
Decentralized	Unit Level	1.0a	1.0c	1.2f	0.6i

Figure 2: Relative comparison of costs by cost head

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.

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 incurres 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/TI/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 3 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.

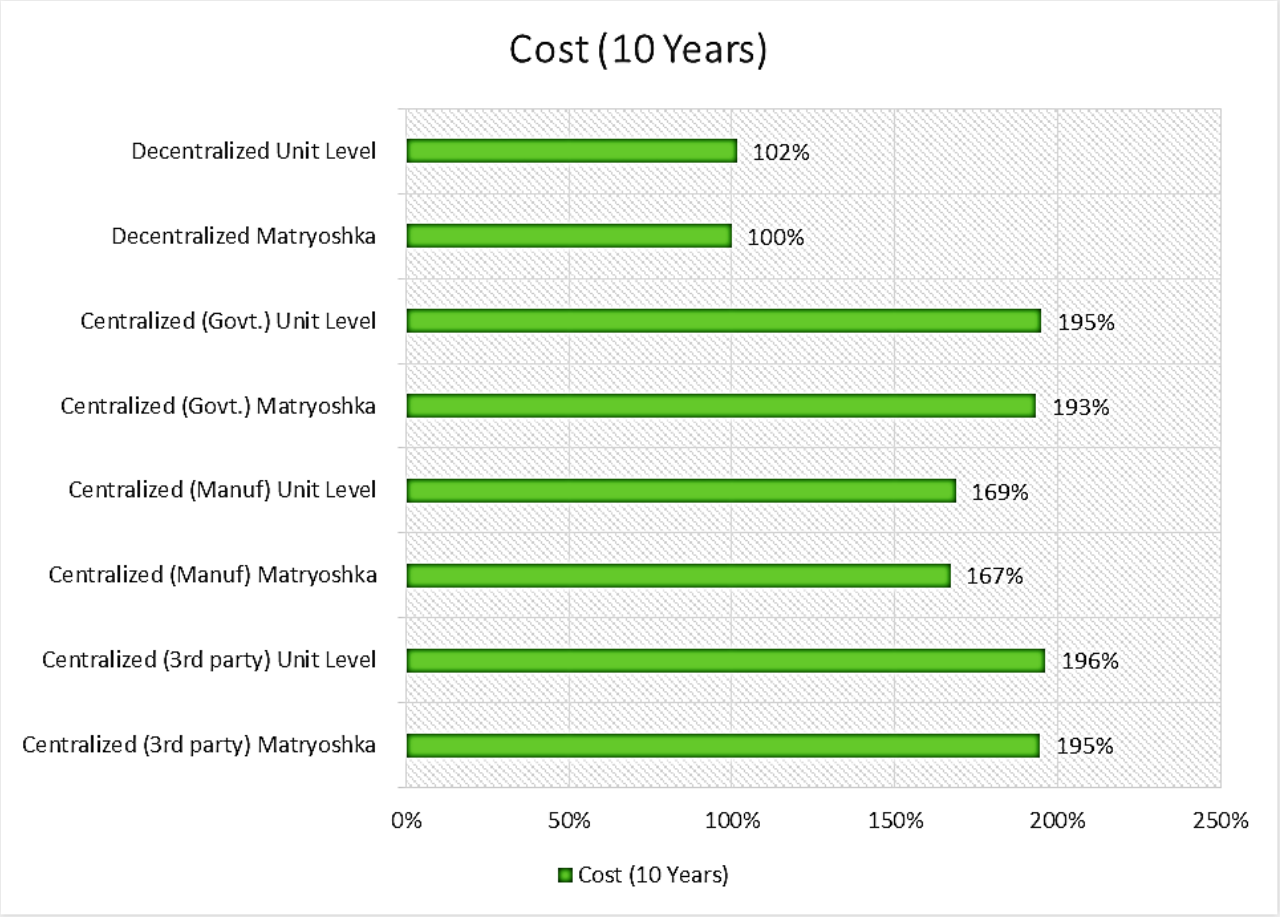

Figure 3: Comparison of cost across all implementation methodologies