A Framework to Evaluate Interoperable Data Exchange Models for Drug Supply Chain Security Act Compliance

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ABSTRACT

The United States has one of the safest drug supply chains in the world. However, its security is threatened by new challenges such as counterfeit, diverted, and illegally imported drugs. To counter the new challenges, the Drug Supply Chain Security Act (DSCSA) was signed into law by President Obama on November 27, 2013, with a 10-year implementation timeframe. As a result, companies in the U.S. pharmaceutical industry, including drug manufacturers, distributors, and dispensers, are challenged to fully comply with the DSCSA by 2023.

The compliance with the DSCSA will enable companies to operate and manage the risks of their supply chains more efficiently. Industry consortiums, such as the Healthcare Distribution Management Association (HDMA), and the industry leaders have recommended various interoperable data exchange models for the implementation of the compliance. However, domestic and international complexities make it difficult to pick the optimal model for the industry.

In this research, we start with categorizing the known data exchange models that can be potentially used by the U.S. pharmaceutical industry. Second, we develop a scorecard methodology based on a framework that considers various factors across the entire supply chain. Next, we examine the categorized models using this scorecard methodology. Lastly, we conclude with recommendations on the data strategy decision for the U.S. pharmaceutical industry.

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1 Introduction

1.1 The New Threats to the U.S. Pharmaceutical Industry

The United States has one of the safest drug supply chains in the world. However, its security is threatened by new challenges such as counterfeit, diverted, and illegally imported drugs. Counterfeit drugs refer to fake medicine that may be contaminated or contain the wrong or no active ingredients (U.S. Food and Drug Administration, 2015). A diverted drug has been illegally transferred between individuals and countries (Wikipedia, 2016).

Global drug sales hover around $1 trillion annually (Thomson Reuters, 2015), and the cost of medicines has become one of the most significant factors for a customer's choice (McLaughlin, 2015). The fact that counterfeit and diverted drugs can be cheaply made and are sold at a fraction of the price of the certified and genuine ones lures a significant number of customers to opt for these drugs. The make-up of the international counterfeit/diverted drug market amounts to around $200 billion annually. Approximately 75 billion represent sales through online marketplaces. Fast growing global illegal drug production, particularly in the emerging economies, and the ease of obtaining counterfeit/diverted medicines has become a menace to the US pharmaceutical industry and continues to threaten patient's safety. About 80% of the counterfeit/diverted drugs consumed in the U.S. originate overseas (McLaughlin, 2015).

In response to new threats to the drug supply chains, the U.S. government has been conducting a number of aggressive initiatives and interdiction efforts to resolve counterfeit, unapproved and/or diverted drugs flowing into the U.S. from abroad by various ways including port entries and express courier hubs. As a result of the U.S. government's efforts, since 2008, Homeland Security Investigations (HSI) on behalf of the U.S. government's Department of

Homeland Security initiated 916 investigations resulting in 334 criminal arrests, obtained 419 indictments and secured 288 convictions with over 3,000 seizures valued at over $195 million (Kubiak, 2014).

1.2 Government Response

To counter the new challenges, the Drug Supply Chain Security Act (DSCSA) was signed into law by President Obama on November 27, 2013, with a 10-year implementation timeframe. As a result, companies in the U.S. pharmaceutical industry, including drug manufacturers, distributors, and dispensers, are challenged to fully comply with the DSCSA by 2023. An interoperable data exchange model is at the heart of the DSCSA. Key aspects of this law cover: 1) the scope of supply chain participants and their requirements for managing and passing transaction information, 2) rules for providing transaction information for investigations and suspect product notifications, 3) rules for trading with authorized supply chain participants, 4) the range of information to be passed as goods change ownership and move through the supply chain, and 5) new requirements to uniquely identify prescription drug products using serialization (Fletcher, 2015). Figure 1 Information Flows in the Drug Supply Chain demonstrates information flows among stakeholders after the implementation of the DSCSA compliance. As a result, the DSCSA requires all the pharmaceutical stakeholders to trade only with authorized distributors, share transaction documents, support product investigations and serialize each product item for unique identification (Fletcher, 2015).

Figure 1 Information Flows in the Drug Supply Chain

1.3 Opportunities of Implementing Compliance

The implementation of compliance will lead to a better information flow across the supply chain. With better information, companies can operate and manage the risks of their supply chains more efficiently. For example, manufacturers will be able to protect their brand and enhance the detection of and notification about illegitimate products; distributors and dispensers will be able to verify the product identifier on the drug package and help protect consumers from counterfeit and illegally imported drugs.

1.4 Challenges of Implementing Compliance

Despite the research efforts that the Healthcare Distribution Management Association (HDMA) and the industry leaders have made towards compliance of the DSCSA, there are still many uncertainties for the next steps.

1.4.1 Lack of Consensus among Stakeholders

The major challenge is how to collect and manage the massive amount of transaction information that will be generated by the unit level serialization data. There are several different

types of stakeholders and participants who must participate in the DSCSA, including drug manufacturers, distributors, dispensers, repackagers and third-party logistics providers. A consensus among all parties is needed in order to construct a model that can fulfill the interoperable data exchange requirements while protecting data privacy. In addition, seamless integration between different stakeholders' systems as well as the design of a new interoperable system to link them are top priorities as market-ready solutions to process serialized products and support unified data models have just begun to roll out. It is technically very difficult to plan and build such a solution and system, from both hardware and software perspectives. Therefore, the pharmaceutical stakeholders must consider solutions from leading data solution providers even before FDA guidelines are published, data standards are fully defined or proposed technologies have been proven to work. Industry stakeholders and regulators will need to work together to define and pilot an interoperable system well in advance of the 2023 compliance date (Fletcher, 2015).

For example, one challenge for distributors and perhaps dispensers as well is the difficulty to manage a large number of units within a pallet. Aggregation at the case and pallet levels are not required by the DSCSA, but if the drug manufacturer can provide the information that maps units to pallets, the efficiency of the supply chain will be greatly improved. However, every coin has two sides. Aggregation information is helpful for efficiency improvement only if the mappings between serial and batch numbers are accurate. For example, if a distributor purchases a pallet of drugs from a manufacturer and the data says there are 100 units of product X on the pallet, when there are only 80, unless the distributor breaks down the pallet and scans each unit they will not catch the error and could potentially sell the incorrect product and/or quantity to their customer, based on the assumption that there are 100 units of product X on the

pallet. In this example, the error would not be detected until each unit is scanned at the dispenser level, which could be several days or weeks later. Despite the limitations mentioned above, the aggregation is still crucial for the industry to operate efficiently as a whole. In order to be able to provide the aggregation information, the manufacturer has to invest capital to upgrade its production system. However, the resulting aggregation information mainly benefits the downstream stakeholders in the supply chain. In order to benefit all parties in the supply chain, the generation of aggregation information requires both financial and operational commitments from everyone. Without these commitments, the investment to generate and maintain such information cannot be justified in the first place.

1.4.2 Lack of Global Standards

In addition to aligning the needs of all stakeholders within the U.S. pharmaceutical supply chain, it is very important to develop global standards and the information systems for these new standards, so that they can be integrated seamlessly within the global manufacturing environments. Each country may have its own unique pharmaceutical regulations and industry environments; optimal data models may need to be flexible and/or vary by country or geographic region. Plus, many of the current U.S. pharmaceutical enterprise systems still fail to accommodate all the global requirements or do not offer the necessary extensibility to allow changes to accommodate the requirements (Fletcher, 2015). Thus, the U.S. government and pharmaceutical stakeholders must carefully consider developing a data model that works extensively with peer systems from other regions and countries on the global level while providing flexibility to accommodate any further needs and changes that may happen in the future. For example, the aggregation requirement varies between different countries. Aggregation is voluntary in the U.S. and South Korea, while it is mandatory in China and Brazil.

1.5 Deciding on the Next Step

Despite the challenges, many possible solutions have been developed to implement compliance. Some of the possible solutions are still conceptual, while some of them are already implemented in foreign countries. The major concern for the next step is not to invent a new solution but to choose a viable solution as the foundation that will allow customizations and innovations in order to best fit the reality of the U.S. market.

Since the best interests of all parties in the industry are not always perfectly aligned, different companies may prefer different data models if the models are evaluated within the scope of individual companies. In other words, if companies aim to maximize their own benefits, without consideration for other stakeholders, the consensus needed to build the data exchange model will be impossible.

Companies should first work collaboratively to decide the best solution for the industry as a whole before they negotiate about how their efforts are best compensated. This dynamic is similar to supply chain optimization where optimizing for a single company is never the best solution.

1.6 Summary

The complexities of drug transaction data management, both domestically and internationally, are the major source of uncertainty to implementing DSCSA compliance. Companies working towards DSCSA compliance should thoughtfully decide on an interoperable data exchange model that addresses the complexities. When choosing among the feasible options, companies should decide collaboratively on a solution that maximizes the benefit for the industry as a whole. Through this research, we will evaluate the known data strategies that can be

potentially used by the U.S. pharmaceutical industry and develop a framework to evaluate these strategies considering the entire supply chain. By examining the known data strategies using our framework, we will conclude our research with recommendations for our thesis partner company on its data strategy decision.

2 Relevant Literature

To formulate the data strategy discussed in the introduction section, we began by referring to a variety of literature. The U.S. pharmaceutical industry is not the first in trying to manage drug transaction data. A plausible data strategy is best built based on the lessons from other countries and should reflect the DSCSA requirements as well as the reality of the U.S. pharmaceutical industry. Transaction data management is part of the supply chain management. A plausible data strategy should organically fit into the holistic supply chain strategy and pass the test of the supply chain evaluation framework as well.

Accordingly, we conducted a literature review of possible data strategies for the U.S. pharmaceutical industry, the DSCSA requirements, the current state of the U.S. pharmaceutical industry, and the supply chain strategy evaluation framework.

2.1 Existing Strategies for Transaction Data Management

The Rx360 white paper has a thorough analysis of the existing data exchange strategies. Rx360, the author of this white paper, is a non-profit organization consisting of volunteers from the Pharmaceutical and Biotech industry, including manufacturers and suppliers (Rx-360, 2015). The organization's mission is to protect patient safety by sharing information and implementing processes for improved pharmaceutical supply chain integrity and material quality in the supply chain. Rx360 formed the Traceability Data Exchange and Architecture Workgroup (TDEA) and

opened it to all interested organizations, including those companies that were not members. The main purpose of the TDEA workgroup was to obtain the broadest possible industry perspective on various data architecture and choreography models. The TDEA began its activities in August 2014 and published a white paper in March 2015 to help improve private sector understanding of how to meet the regulatory requirements in the most efficient and patient-focused manner. The white paper referenced several data exchange models for the industry to consider in an effort to drive alignment around a preferred model (Rx-360, 2015).

2.1.1 Three Data Exchange Models

Although the transaction data management strategies used in various countries are different from one to another, they all fall into three categories: centralized, semi-centralized, and distributed.

2.1.1.1 The Centralized Model

The centralized model employs a central repository in which all stakeholders store their transaction data (Rx-360, 2015). More details about this model are shown in Figure 2.

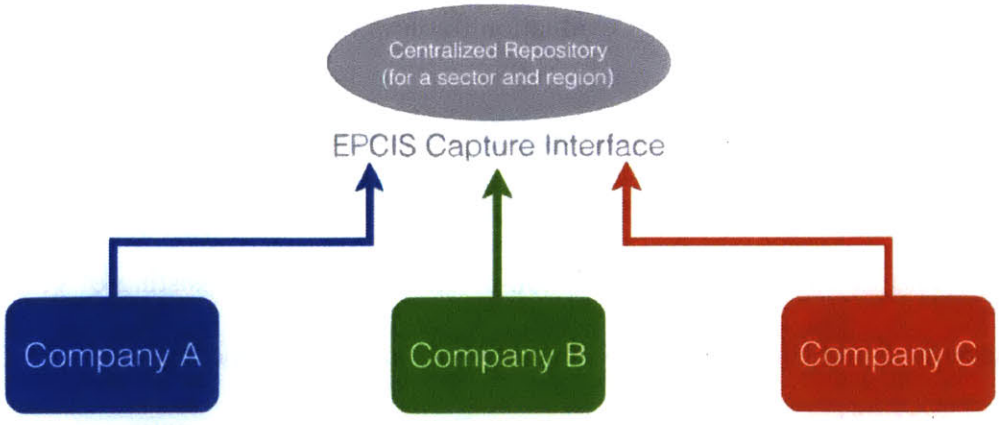

Figure 2 The Centralized Model (Rx-360, 2015)

2.1.1.2 The Semi-centralized Model

The semi-centralized model stores transaction data in different repositories that are selected according to certain criteria (Rx-360, 2015). Depending on implementation details, a hub system might be created to connect all the repositories.

The location of the repository to store transaction data can be decided in many different ways. One such way is based on relative positions along the supply chain; for instance, the data can be stored in the repository belonging to the last stakeholder handling the specific product. Another possibility is to store the data in the repository of one of the most influential stakeholders in the supply chain, which is usually the manufacturer or distributor. Once the repository is decided, transaction data will be sent to that specific repository (Rx-360, 2015).

Once the location of the repository is decided, the next step is to decide what transaction data should be stored in a given repository. Similar to the decision of locations, deciding transaction data also involves flexible criteria. For example, one system can capture one drug supply chain, or the supply chains of multiple drugs that are similar in some respect. Another way to do this is to segment by geographical location/country (Rx-360, 2015). Figure 3 The Semi-Centralized Model shows a diagram of the semi-centralized model.

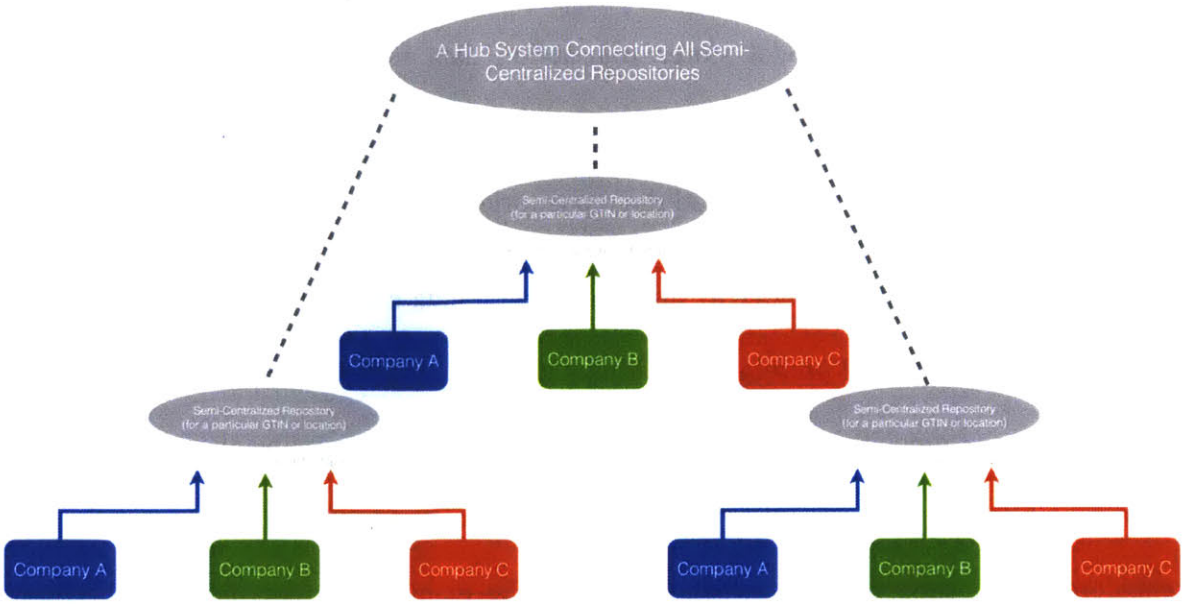

Figure 3 The Semi-Centralized Model (Rx-360, 2015)

2.1.1.3 The Distributed Model

The third strategy is the distributed model, where each data creator stores its transaction data in its own repository so that it can be queried to obtain data required for reporting (Rx-360, 2015). The distributed model is shown in Figure 4 The Distributed Model .

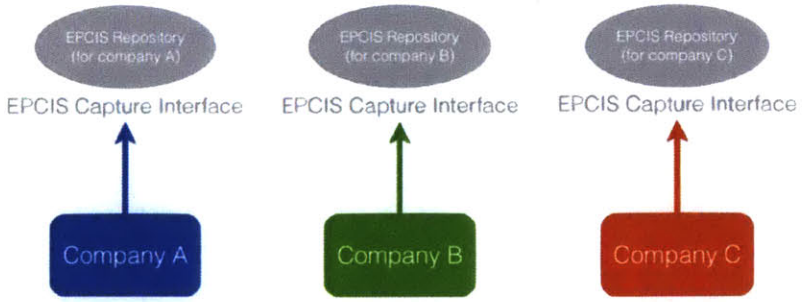

Figure 4 The Distributed Model (Rx-360, 2015)

2.1.1.4 The Differences between the Three Models

The most distinct difference between the centralized, semi-centralized, and distributed data models comes from the number of places to store transaction data. The centralized model employs only one place of storage, whereas the semi-centralized and distributed ones use multiple repositories; the distributed model allows every stakeholder to keep the transaction data they create, whereas the centralized and semi-centralized ones require transaction data to be stored in the specified repository (Rx-360, 2015).

The locations of transaction data are obvious in the centralized and distributed models, but vague in the semi-centralized one. In the distributed model, transaction data is saved in the repositories owned by the data creators (Rx-360, 2015). In the centralized model, transaction data is stored in a single repository that is shared by all stakeholders. In the semi-centralized model, transaction data is kept in specified repositories that are decided by rules discussed earlier (Rx-360, 2015).

2.1.2 Implementations in Foreign Countries

According to the Rx360 white paper, the U.S. is not the only country to implement regulations for securing drug supply chains. There are six other countries and regions where drug tracking has been implemented, namely the European Union, Argentina, Brazil, Turkey, China and South Korea. Besides drug security, the transaction data is also used to verify the accuracy of medical reimbursements in some countries, including Turkey and China.

China and South Korea have picked the centralized strategy, where the government is responsible for building and managing their data model. For example, the Chinese government has been developing the Chinese Electronic Drug Monitoring Code (EDMC) to centrally monitor and control all drug sales data in the country (Rx-360, 2015).

In addition, the EU is implementing the semi-centralized strategy (Rx-360, 2015). The EU model has a hub system, known as the European Hub, and different repositories. These different repositories store transaction data generated in different countries, while the European Hub provides interconnection between the different national repositories. The European Hub and the national repository systems are funded by the manufacturers, while those systems interacting with serial numbers for verification are funded by distributors and pharmacies. All data posted to a data repository is owned by the creator and not by the government. Access to another party's data is allowed only for verification purposes (Rx-360, 2015).

2.2 The U.S. Marketplace

Before the U.S. government enacted the DSCSA legislation, the HDMA, a U.S. national pharmaceutical industry association, launched a three-phase initiative to study and encourage product data sharing in the healthcare industry. This effort to secure the drug supply chains was undertaken in late 2005 (HDMA Foundation, 2007). The respective Phase I white paper was published in early 2007 to show various stakeholders' opinions on data sharing in the pharmaceutical industry. The Phase II white paper was published in late 2007 to design a blueprint for data sharing and management and suggested the Electronic Product Code Information System (EPCIS) as the data sharing protocol. The Phase III white paper is still in progress (HDMA Foundation, 2007).

The Phase II white paper later became the backbone of the DSCSA, further stimulating the U.S. government's efforts to protect drug users and the pharmaceutical companies in a response to growing needs from the industry and individuals. In addition, the Phase I white paper revealed the results of the research conducted by the Center for Supply Chain Management at Rutgers University (HDMA Foundation, 2007).

According to the HDMA Phase I white paper, motivations for sharing item-level transactional product data across the supply chain are strong, while concerns about the sharing of confidential data and protecting the privacy of patient and business information are equally evident (privacy). Most participants in Phase I believed that the product track-and-trace capability is an important component that can further enhance patient safety and the continued security of the supply chain. They believed that a complete solution would encompass proper storage and handling of all products, coordinated legislative and regulatory requirements and additional safeguards to further ensure that the right products are given to the right patients at the right times (patient safety). To all participants, compliance with government requirements is the most immediate benefit (compliance). Participants also identified other benefits (operational efficiency), such as potential cost reductions in product returns and recalls, inventory management efficiencies, improved forecasting capabilities, increased service levels, reduced out-of-stock items and overall reduced operating costs. (HDMA Foundation, 2007)

The limitation of this report is that it only considers the domestic market environment. However, we believe that companies should also consider compliance with international regulations (international compliance) when implementing compliance. In addition, solutions from other markets can be leveraged if appropriate.

In summary, the U.S. pharmaceutical industry is generally concerned about five dimensions when implementing compliance with the DSCSA: compliance, patient security, privacy, operational efficiency, and international compliance.

2.3 Supply Chain Strategy Evaluation Frameworks

Companies in the U.S. pharmaceutical industry, including drug manufacturers, distributors, and dispensers, are challenged to fully comply with the DSCSA by 2023. The interoperable data exchange model for drug supply chain data is key to compliance. However, industry has not yet agreed on the details of the exchange model, including what data is mandatory to share, who implements which part of the system, who owns the data, and how the data will be managed and shared.

Given the conflicting interests in these multiple dimensions, picking an optimal supply chain data exchange model requires objective decision-making procedures based on multi-faceted and wide scenario-based criteria. Without a clearly defined framework and strategy, it is impossible to make clear decisions. The strategy's quality is as important as the existence and validation of the strategy itself because a biased, unproven strategy may jeopardize and limit a company's growth potential in the long run, even if it might help with decision making in response to the DSCSA in the short term. It is, however, nearly impossible to identify an optimal strategy for all the players in the pharmaceutical industry because strategies may vary with each company's business vision and operational reality. Therefore, we will focus on a systematic and objective evaluation of strategies in our research. Before formulating our own evaluation framework, we reviewed some works of leading thinkers on strategy evaluation.

2.3.1 Influential Strategy Evaluation Frameworks

After an extensive and careful search for optimal strategy formulation and evaluation guidelines for data collection/management and for supply chain optimization, we have identified a few candidate approaches, which can be potentially used as the foundation of our own strategy evaluation framework.

The modern study of strategy formulation and evaluation began with an article published in *Harvard Business Review by* Tilles in 1963. Unlike earlier researchers, who emphasized vision, management style, and/or management practice, Tilles advocated six measurable standards for strategy formulation and evaluation: 1) internal consistency, 2) consistency with the environment, 3) appropriateness in the light of available resources, 4) satisfactory degree of risk, 5) appropriate time horizon, and 6) adequacy of results achieved (Tilles, 1963).

Tilles' framework was a break-through in terms of structured strategy formulation and evaluation, but it is highly dependent on specific cases/anecdotes and is not easy to apply in practice (Rumelt, 1979). Generalizations and tactical theories are needed for these six standards to apply to all industries and scenarios (Rumelt, 1979).

Rumelt recommended four generalized evaluation criteria that can be used to rule out flawed strategy proposals. According to Rumelt, a plausible strategy must 1) be internally consistent, 2) provide for consonance between the firm and its environment, 3) be based on the gaining and maintenance of competitive advantage, and 4) be feasible in the light of existing skills and resources (Rumelt, 1979). This proposal was initially published in 1979 and refined later in 1998. Although somewhat in line with Tiles' proposal, Rumelt's only suggests what to avoid in strategy evaluation.

Finally, as part of the MIT Supply Chain 2020 Project, the Center for Transportation and Logistics at MIT developed a working model for rethinking supply chain strategy (Perez-Franco, 2016), which is an extensive framework for supply chain strategy formulation and evaluation. The main idea is that a company should develop a globally optimized supply chain strategy considering multiple factors. At the heart is the organization's business strategy, supported by the supply chain strategy and supply chain operations. Around them are the assets, culture, and

capability of the company, encapsulated by corporate guidelines, market dynamics, and industry context (Perez-Franco, 2016). For brevity, we will refer this model as the SC2020 framework in the rest of this thesis.

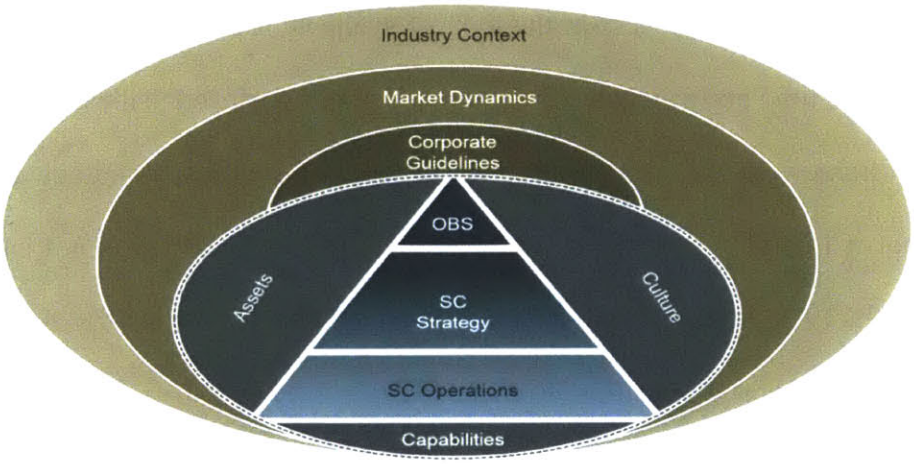

Figure 5 A Working Model for Rethinking a Supply Chain Strategy (Perez-Franco, 2016)

2.3.2 Feasibility Considerations

We have seen that Tilles' work sets a new standard for strategy evaluation frameworks but may not be very applicable to our research. Similarly, although Rumelt's work provides a tactical way to apply the framework, it is heavily focused on eliminating flawed candidates. Thus, neither provides a comprehensive framework for our research. We propose to employ the SC2020 framework for our strategy evaluation and formulation because it provides the most complete and comprehensive framework that is the most applicable to the current reality and issues of the U.S. pharmaceutical industry. As transaction data sharing is part of the supply chain, we plan to use the SC2020 framework to map out our criteria and use it to evaluate the three data exchange candidates – the centralized, semi-centralized, and distributed models.

3 Methodology

Compliance with the DSCSA is not just a mandatory requirement but also an opportunity for pharmaceutical companies to better manage their supply chain risks. Different data sharing models imply different costs and efficiencies. In our research, we will show these differences by developing a balanced scorecard, against which all three data models will be rated and compared.

3.1 The Balanced Scorecard Method

The balanced scorecard is a strategic planning and management system that is used extensively in business and industry, government, and nonprofit organizations worldwide. It is designed to align business activities with the vision and strategy of the organization, improve internal and external communications, and monitor organization performance against strategic goals. It was created by Dr. Robert Kaplan and Dr. David Norton of Harvard Business School as a performance measurement framework that added strategic non-financial performance measures to traditional financial metrics in order to give managers and executives a more "balanced" view of organizational performance. While the term "balanced scorecard" was coined in the early 1990s, the roots of this type of approach reach further back and include the pioneering work of General Electric Corporation on performance measurement reporting in the 1950's, as well as the work of French process engineers (who created the Tableau de Bord – literally, a "dashboard" of performance measures) in the early part of the 20th century.

3.2 The COSPI Scorecard

In the literature review section, we have identified five dimensions to be considered: compliance with the DSCSA, drug security, privacy, international compliance, and operational efficiency. Next, we will break down these dimensions into tangible and measurable criteria that

will be used to construct our scorecard. Since the scorecard is constructed based on the five dimensions, we name it after these dimensions: **C**ompliance, **O**perational efficiency, **S**ecurity, **P**rivacy, and **I**nternational compliance (COSPI). The following sections present these dimensions in detail.

3.2.1 Compliance with the DSCSA

According to the DSCSA, product-tracing requirements for downstream pharmaceutical supply chain members are:

1) Drug manufacturers, distributors, and dispensers will be required to pass on certain information and representations about pharmaceutical transactions when there is a change of ownership
2) Drug manufacturers, distributors, and dispensers may only accept the product if this information is provided
3) Drug manufacturers, distributors, and dispensers will be required to engage in verification and notification activities in circumstances pertaining to suspect and illegitimate products
4) Drug manufacturers, distributors, and dispensers will be required to promptly respond to requests for information from the Secretary, or another State or Federal official, in the event of a recall or investigation of a suspect or illegitimate product, and to keep records of investigations of the suspect and/or illegitimate product. However, instead of imposing one-size-fits-all requirements, requirements are tailored to the supply chain members to reflect the different and unique roles that each sector plays in the pharmaceutical distribution supply chain

5) Manufacturers, repackagers, and wholesale distributors will be required to respond to requests to verify product at the unit level in circumstances pertaining to suspect and illegitimate product and must also enable product verification at the unit level for sellable returns once the product is serialized
6) Third-party logistics providers provide warehouse or other logistics services and do not take ownership of the product. However, they will be required to accept information from the product owner before accepting the product, and will need to alert the owner in the case of a suspect or illegitimate product.

Table 1 summarizes the capabilities needed for the compliance dimension. Since the DSCSA is a high-level guideline, its implied requirements are more abstract than those identified in later sections. For example, we mentioned the ability to share unit level information upon request in this section and in the security section, we will mention the ability to verify the unique identifiers of the drug when the drug is shipped. The first capability is automatically met as long as the second one is satisfied. Therefore, there are duplications between capabilities identified in this section and those identified in other sections, including operational efficiency, security, and privacy. We have decided to leave this duplication because compliance is of high importance.

Table 1 Capabilities Needed for the Compliance Requirements

Stakeholders	Required Capabilities
Third-party Logistics Providers	Verify the integrity of transaction information before taking over the custody of the product Notify related stakeholders upon incompliance
Manufacturer, Distributor, and Dispenser	Share unit level information upon request [1] Provide transaction information when transferring ownership Verify the integrity of transaction information before taking over the ownership Share transaction information in a timely manner upon request Record investigation history

NOTE [1] – Sharing information with the government is a compliance requirement, but stakeholders in the supply chain may only have visibility to transaction information for product they sell or receive.

3.2.2 Operational Efficiency

Besides managing the supply chain risk, operational efficiency improvement is another benefit of compliance. Scenarios under this category include:

1) Drug recall
2) Inventory management.

3.2.2.1 Drug Recall

This scenario requires the ability to trace the drugs downstream through the supply chain and the ability to notify the affected entities. By 2023, the data should be available but not accessible by all of the supply chain participants when it is needed. For example, in a recall scenario, the manufacturer may not have timely or accurate visibility/access to shipping information from the distributor to the dispenser but the distributor should have this information and be required to notify their customers at the time of recall or make the information accessible to the manufacturer or regulatory agencies. Recall executions in a timely manner, for patient safety reasons, should be considered when selecting an optimal model.

Assuming that the recall is based on production batches/lots, the manufacturer should implement a method to map the serial number attached to the smallest sellable unit to its production batch/lot. For efficiency reasons, mappings from unit to case or pallet are also needed depending on the package size. The recall can happen any time after the production as in the following scenarios.

1) Before the drug is shipped to the distributor:

The manufacturer identifies the storage location of the problematic units. To do that, the manufacturer should be able to map the lot number to the serial number, then to the storage location.

2) When the drug is shipped to the distributor/dispenser but has not arrived:

In most cases, the manufacturer notifies the distributor/dispenser to reject the problematic drugs. In rare cases, the manufacturer recalls the truck directly. Recalling the truck is uncommon for two reasons. First, this requires a high level of control over the shipment, such as GPS tracking of trucks, mobile numbers for the drivers and the driver's dispatch, which is practiced by the major players in the pharmaceutical industry. Second, the decision to recall the truck is dependent on multiple factors. For example, by the time information about a recall is communicated, received and the appropriate measures decided, a truck shipment en route for same day delivery may have reached its destination before it can be intercepted. Alternatively, the truck may be so close to its destination that it does not make sense to turn it around. In either case, the manufacturer should know which pallet is shipped to which distributor/dispenser. In both cases, the contacts of the distributor/dispenser are needed for coordination purposes. For example, even if the truck is recalled directly, the manufacturer still needs to contact the distributor/dispenser to communicate about potential delivery schedule changes. Contacting the truck driver is part of the manufacturer's transportation operation and will not be considered in this research for data exchange model evaluation.

3) When the drug is received by the distributor/dispenser but has not been shipped out:

The manufacturer provides the recall process and the serial number of problematic drugs, as well as pallet or case serial numbers for efficiency reasons. The distributor/dispenser

locates the problematic drugs and initiates the ship-back. The recall processing company verifies the quantities of the ship-backs and records the serial numbers of destroyed drugs. In this case, it is the manufacturer's responsibility to provide contact information of the recall processing company to the affected distributors/dispensers, so that they can pass the information about recalled units down the supply chain. The recall processing company should also receive the information about recalled units for verification purposes and to ensure that the returned drugs are correct.

4) When the drug is shipped from the distributor to the dispenser but has not arrived:

Two possible cases: a) the distributor recalls the shipping truck; b) the distributor notifies the dispenser to reject the problematic drugs. As discussed earlier, in both cases, the distributor should know which unit shipped to which dispenser and the contact of the dispenser.

5) After the drug is received by the dispenser and before being dispensed:

The manufacturer/distributor should notify the dispenser about the serial number of problematic drugs. The dispenser should be able to identify the drugs according to the serial number and arrange ship-back. The recall processing company should be able to verify the ship-backs and record the destroyed units.

6) After the drug is dispensed:

The dispenser should know which unit was sold to which patient and the contact information of the patient. The recall processing company should be able to verify the returns and record the destroyed units.

Table 2 summarizes the capabilities needed by each stakeholder of the supply chain in order to perform a tracked drug recall. We did not describe in detail how to map the pallet/serial number to the storage location at the manufacturer. The reasons are as follows:

1. Implementation could vary across companies
2. The cost of implementation might vary with the type of data model, but implementation details do not affect the selection of criteria.

Table 2 Capabilities Needed to Perform a Tracked Drug Recall

Stakeholders	Required Capabilities
Manufacturer	Map production lot number to serial number Map serial number to pallet/case number Map serial number to storage space Map serial number to receiving distributor Map serial number to receiving dispenser Store/provide contact information of receiving dispenser Store/provide contact information of receiving distributor Store/provide contact information of the recall processing company
Distributor	Map serial number to pallet/case number Map serial number to the storage space Map serial number to receiving dispenser Store/provide contact information of dispenser
Dispenser	Map serial number to pallet/case number Map serial number to the storage space/retail branch Map serial number to patient Store/provide contact information of patient
Recall Processing Company	Map serial number to pallet/case number Map serial number to distributor/dispenser/customer Record destroyed serial number

3.2.2.2 Inventory Management

A side effect of data serialization is that companies can have easy access to their inventory data. Depending on which data model is used, the cost of retrieving the aggregated

inventory data may be different. Therefore, we will examine the implied cost of retrieving aggregated inventory data in the three data sharing models.

Table 3 summarizes the capabilities required for inventory management.

Table 3 Capabilities for Inventory Management

Stakeholders	Required Capabilities
Manufacturer, Distributor, and Dispenser	Retrieve the aggregated inventory data

3.2.3 Security

Scenarios under this category include:

1) Diverted and counterfeit drugs
2) Stolen drugs
3) Source trace back and compliance supervision.

These scenarios are examined below.

3.2.3.1 Diverted and Counterfeit Drugs

Diverted and counterfeit drugs can both be detected by drug source verification. Due to potential conflicts of interest, distributors and dispensers are not preferred sources for verifying the authenticity of the drugs. For example, a compromised distributor can up-label a drug and sell it at a higher price for a higher top line. A dispenser can use fake/diverted drugs for a lower bottom line.

Strictly speaking, authenticity of the product cannot be verified unless visual inspection and chemical testing are performed. However, the serial number can be verified against the lot

number and expiration date to ensure that it was issued by the manufacturer for the named product. This would be the first step in authenticating a product.

It is not just dispensers who need to verify the authenticity of drugs. Dispensers need to verify the authenticity of drugs before dispensing to best protect their patients. Manufacturers also have the need to verify whether downstream supply chain partners are selling counterfeit drugs under the manufacturers' names.

In order to be able to detect diverted and counterfeit drugs, 1) a serial number must be attached to the smallest sellable units, 2) the drug manufacturer must offer an interface to verify the authenticity of the ID each time the drug is shipped, 3) any change of ownership must be reported, 4) the transaction history must be recorded, and 5) all stakeholders in the supply chain should be able to verify the authenticity of drugs.

Table 4 summarizes the capabilities needed to detect diverted and counterfeit drugs:

Table 4 Capabilities to Detect Diverted and Counterfeit Drugs

Stakeholders	Required Capabilities
Manufacturer	Make serialization data available to verify the authenticity of the drug when the drug is shipped Make sure the verification interface is not compromised (e.g. hacked by fake dealers so that fake drugs can be verified as authentic ones)
Manufacturer, Distributor, and Dispenser	Verify the authenticity of the drug according to its serial number

3.2.3.2 Stolen Drugs

This scenario requires the ability for the victim to report the stolen drugs and for other stakeholders to verify whether drugs are stolen before accepting them, and both are required. If there is only the ability to report the stolen drugs, the receiving party will not be able to identify

an illegal source as long as forged documents are provided. Similarly, if there is only the ability to verify, the stolen drugs will not be detected since no data on stolen drugs is available in the system in the first place. There is a vulnerable time window between when the drug is stolen and when the drug theft is reported. During this period, the drug can still be received by supply chain partners unaware of the theft. Therefore, the victim, who is responsible for reporting the theft, has the motivation to minimize the vulnerable time window so that the entity can minimize its loss.

Table 5 summarizes the capabilities required to handle stolen drugs.

Table 5 Capabilities for Managing Stolen Drugs

Stakeholders	Required Capabilities
Manufacturer, Distributor, and Dispenser	Report the serial numbers of stolen drugs Verify if the received drugs are stolen ones

3.2.3.3 Source Trace Back and Compliance Supervision

This scenario covers when there is a need to trace back the source of the drug, which can happen for various reasons. For example, the regulatory authority may require the industry to trace back the source of a drug that is discovered to be problematic on the customer side. Tracing back drug to their source can be achieved as long as the mechanism described in the "diverted and counterfeit drugs" section is implemented. The problem is identified by reconciling the data across the supply chain so as to pinpoint any inconsistency.

Table 6 summarizes the capabilities required for compliance supervision.

Table 6 Capabilities for Source Trace Back and Compliance Supervision

Stakeholders	Required Capabilities
Regulator	Verify data consistency of investigated drugs across the supply chain

3.2.4 Privacy

This category includes:

1) Proprietary business information protection
2) Patient privacy protection.

Privacy can be threatened by a compromised system (e.g. someone hacks into the system and steals data) or improper data access (e.g. someone who has regular database access authority accesses data for malicious or unauthorized purposes). Although the risk of a compromised system exists regardless of which data sharing model is used, we still need to consider this point because different data sharing models will imply different costs to secure the system.

Protection of business proprietary information is our major concern, because patient privacy, governed and protected by the HIPAA law (Health Insurance Portability and Accountability Act), is not supposed to be part of DSCSA compliance.

Table 7 summarizes the capabilities required for privacy protection.

Table 7 Capabilities for Privacy

Stakeholders	Required Capabilities
Manufacturer, Distributor, and Dispenser	Secure the system so that the data is not easily hacked and stolen Grade the privacy level of the submitted information Disclose the information based the information requester's privacy access level

3.2.5 International Compliance

Given the fact that more and more manufacturers have a global supply chain, it is also important that the data sharing model has the flexibility to be adapted to meet other countries' compliance requirements.

The implementation-level flexibility can be realized by modulation technologies, and the details about modulation technologies are out of the scope of this research. We need to keep the support of modulation technologies as one of our criteria because different data sharing models will imply different costs to implement the modulation technologies.

Table 8 summarizes the capabilities required for international compliance.

Table 8 Capabilities for International Compliance

Stakeholders	Required Capabilities
Manufacturer, Distributor, and Dispenser	Support modulation technologies for easy adaption to international compliance requirements

3.2.6 Summary of Required Capabilities

By assembling the implied capabilities listed in previous sections and removing redundancy, we obtain the list of implied capabilities shown in Table 9. Getting the contact of a certain stakeholder is not relevant to the interoperable data sharing model, therefore, the respective points will be excluded in future discussions. Mapping drugs to a patient is governed by other laws and therefore is out of scope. Mapping serial numbers to a receiving dispenser is a duplicate capability for manufacturers and distributors, and, therefore, we merge these two lines into one.

Table 9 Capabilities Implied by the COSPI Criteria

Stakeholders	Required Capabilities
Manufacturer, Distributor, and Dispenser	Disclose information based the information requester's privacy access level
	Grade the privacy level of the submitted information
	Make serialization data available to verify the authenticity of the drug when the drug is shipped
	Make sure the verification interface is not compromised (e.g. hacked by counterfeit drug dealers so that counterfeit drugs can be verified as authentic ones)
	Map serial number to pallet/case number
	Map serial number to the storage space/retail branch
	Provide transaction information when transferring ownership
	Record investigation history
	Report the serial number of stolen drugs
	Retrieve the aggregated inventory data
	Secure the system so that the data is not easily hacked and stolen
	Share unit level information upon request
	Support modulation technologies for an easy adaption to international compliance
	Share transaction information in a timely manner upon request
	Verify if the receiving drugs are stolen ones
	Verify the authenticity of the drug according to its serial number
	Verify the integrity of transaction information before taking over the ownership
Distributor	Store/provide contact information of dispenser [1]
	Map serial number to receiving dispenser [2]
Manufacturer	Map serial number to receiving dispenser [2]
	Store/provide contact information of receiving dispenser [1]
	Store/provide contact information of receiving distributor [1]
	Store/provide contact information of the recall processing company [1]
	Map production lot number to serial number
	Map serial number to receiving distributor
Dispenser	Map serial number to patient [1]
	Store/provide contact information of patient [1]
Recall Processing Company	Map serial number to the returning company
	Map serial number to pallet/case number
	Record destroyed serial number
Third-party Logistics Providers	Notify related stakeholders upon incompliance
	Verify the integrity of transaction information before taking over the ownership
Regulator	Verify the data consistency of investigated drugs across the supply chain

NOTE [1] These items will be eliminated due to them being irrelevant, as discussed in the text.
NOTE [2] These two items will be consolidated into one item, as they are duplicates.

3.3 Scoring Rules

For each required capability, we will assign a score on a scale of 1 to 5. This scale has been arbitrarily decided based on the limited complexity due to our qualitative analysis.

3.3.1 Two Types of Related Costs

Scores are decided based on a qualitative analysis of two types of costs that are related to the interoperable data sharing model: upfront and on-going cost. Each cost is examined on one dimension of Table 10 Scoring Rules.

a. The upfront cost to set up the relevant software

Complying with the DSCSA requires acquiring new capabilities for processing transaction data. Given the large size of transaction data, these capabilities can only be acquired with the aid of new software systems.

Companies can choose to build their own systems separately or to collaborate to build shared systems. If companies choose to build shared systems together, a cost sharing synergy appears. Depending on who builds these shared systems, the synergy can be achieved in different manners. If the shared systems are built by one of the companies working towards compliance, the other companies can share the system development cost so that each party has access to the new systems at a lower cost. If these shared systems are built by a third-party software service provider, all the companies working towards compliance can negotiate jointly to obtain a lower price, and share the cost of the third-party software.

Not all three data sharing models allow companies to build shared systems collaboratively. Therefore, the potential cost sharing synergy varies with the choice of the data sharing model.

b. The on-going cost to use the relevant software on a daily basis

Another cost associated with compliance is the day-to-day effort interacting with the software systems and the transaction data stored in these systems.

The day-to-day interactions involve reference activities and maintenance efforts. *Reference activities* do not require significant efforts; one example of a reference activity is the retrieval of transaction data from the system for reporting purposes. On the other hand, some of the *maintenance activities* only require efforts from individual companies, such as inputting newly generated transaction data into the system. Other maintenance efforts require collaboration between different companies, which means higher costs due to the need to coordinate multiple parties. In some of the collaboration-based maintenance scenarios, the coordinator is obvious. One example of such a scenario is the decision of when to update the system. In other scenarios, any company involved can potentially play the coordinator's role. One example of such a scenario is the decision of who has access to what transaction data. In general, collaboration efforts without an obvious coordinator are more costly than those with an obvious coordinator.

Depending on the choice of data sharing models, the day-to-day interaction cost or on-going cost may vary in four different ways: 1) no on-going maintenance effort needed, 2) need maintenance effort from an individual company, 3) need maintenance effort from multiple companies and the coordinator is obvious, and 4) need maintenance effort from multiple companies but the coordinator is not obvious.

3.3.2 Setting the Scores

The more a data sharing model costs, the less favorable the model is, and therefore, the lower the score the model will get. The right-bottom cell of Table 10 Scoring Rules has the highest upfront and on-going cost. Therefore, it's assigned the lowest possible score, which is 1. Of the two neighbors of the right-bottom cell, one has lower upfront cost, while the other has lower on-going cost. Since there is no evidence showing the qualitative difference between a lower upfront cost and a lower on-going cost, we arbitrarily assign these two cells the second lowest score, which is 2. Similarly, the scores for the remaining cells are decided following the same process and rationality.

Table 10 Scoring Rules

	Variable / On-going Cost				
Fixed / Upfront Cost		No on-going maintenance effort needed	Need maintenance effort from an individual company	Need maintenance effort from multiple companies and the coordinator is obvious	Need maintenance effort from multiple companies but the coordinator is not obvious
	Has cost sharing synergy	5	4	3	2
	No cost sharing synergy	4	3	2	1

3.3.3 Interpretation of the Scores

Since the analysis is qualitative, the values of the scores are just indicators of the relative performance of a particular model. They do not have any meaning by themselves, neither are they representative of nor proportional to the actual costs.

3.4 Examining the COSPI Scorecard Using the SC2020 Framework

The COSPI Scorecard is coherent with the SC2020 framework. In the SC2020 framework, a company should develop a globally optimized supply chain strategy considering multiple factors, including company goals and capability, corporate guidelines, market dynamics and industry context. The COSPI Scorecard covers all these factors. Table 11 demonstrates the overlap between the COSPI criteria and the major categories of the SC2020 framework. Overlaps are marked by "X" in Table 11.

Table 11 Examining the COSPI Scorecard Using the SC2020 Framework

	Compliance	Operational efficiency	Security	Privacy	International compliance
Company goals and capability	X	X	X	X	X
Corporate guideline	X		X	X	
Market dynamics		X	X	X	X
Industry context	X		X	X	X

4 Results

4.1 The Scoring Process

Regardless of their origins, the 26 required capabilities from the COSPI framework fall into 4 categories according to the types of actions they need. Each category has the same scoring pattern, as described in the following sections.

4.1.1 Writing and Security Capabilities

Writing capabilities refer to capabilities that require inputting data into the system. The entity creating the transaction data not only assumes the data ownership but also inputs the data into the system. Since data is input by the entity that creates it, only one entity is involved.

Security capabilities refer to those that require the software system maintainer to take actions to secure the software system. Since the maintainer is usually the owner of the system, only one company is involved in this activity.

Both capabilities involve efforts only from one company. Therefore, the corresponding scores should be picked from the second column (3 or 4) of Table 10 Scoring Rules. The centralized and semi-centralized models have cost-saving synergies, while the distributed model does not. Depending on whether the upfront cost can be shared, the scores are 4 or 3. Respective capabilities, marked in "W/S" the type column in Table 12 The Evaluation Results, include:

- Make serialization data available to verify the authenticity of the drug when the drug is shipped
- Provide transaction information when transferring ownership
- Record investigation history
- Report the serial number of stolen drugs
- Record destroyed serial number
- Retrieve the aggregated inventory data
- Make sure the verification interface is not compromised (e.g. hacked by fake dealers so that fake drugs can be verified as authentic ones)

- Secure the system so that the data is not easily hacked and stolen.

4.1.2 Reading Capabilities

Reading capabilities are those that require retrieving data from the system. Retrieving data usually does not require extra maintenance effort, and therefore, the scores should be picked from the first column of Table 10. Depending on whether the upfront cost can be shared, the scores are 5 or 4. Respective capabilities, marked in "R" in the type column in Table 12 The Evaluation Results, include:

- Share unit level information upon request
- Share transaction information in a timely manner upon request
- Map serial number to pallet/case number
- Map serial number to the storage space/retail branch
- Map serial number to receiving dispenser
- Map production lot number to serial number
- Map serial number to receiving distributor
- Map serial number to the returning company
- Map serial number to pallet/case number
- Verify if the receiving drugs are stolen ones
- Verify the authenticity of the drug according to its serial number
- Verify the integrity of transaction information before taking over the ownership
- Verify the integrity of transaction information before taking over the ownership
- Verify the data consistency of investigated drugs across the supply chain.

4.1.3 Administrative Capabilities

Administrative capabilities denote those that decide the permission for each user of the system. Due to the distributed data ownership, permissions should be defined based on a consensus among all stakeholders. Therefore, defining permissions needs collaboration between multiple companies. Permissions in the semi-centralized model are easier to negotiate, because drugs in the same instance of a semi-centralized model are often similar to each other: these drugs are either from the same manufacturer or sold by the same distributor or dispenser. Therefore, the score for the semi-centralized model comes from the third column (2 or 3) of Table 10 Scoring Rules, and the scores for the centralized and distributed models come from the

fourth column (1 or 2). As with the previous two types of capabilities, the upfront cost can be shared in the centralized and semi-centralized models, but cannot be shared in the distributed model. Therefore, the scores for the centralized, semi-centralized and distributed models are 2, 3 and 1, respectively. Respective capabilities, marked "A" in the type column in Table 12 The Evaluation Results, include:

- Disclose the information based the information requester's privacy access level
- Grade the privacy level of the submitted information
- Notify related stakeholders upon incompliance.

4.1.4 Other Capabilities

The only capability that cannot be covered by the previous three categories is the support of modulation technologies for easy adaption to international compliance requirements. It is different from all other capabilities due to the complexity of international compliance.

There are two barriers preventing companies from sharing costs of their international data exchange models with other multinational peers or with other subsidiaries from different countries. First, different companies have different scopes of international markets. As a result, efforts towards international compliance may vary between companies. Unlike domestic compliance with the DSCSA, international compliance is not uniform across all companies. Therefore, the cost-sharing synergy among companies for international compliance, if any, is much lower than the synergy for domestic compliance. Second, each country has different regulations, which in general require unique and specific customization for full compliance. For a company that has one unified data model for its subsidiaries from different countries, updating software used in one country due to regulation changes will automatically impact software and compliance for other countries. Therefore, the cost-sharing synergy among subsidiaries is minimal.

In summary, the capability to support modulation technologies for an easy adaption to international compliance has a low cost-sharing synergy, if any, regardless of the data sharing model. And implementing this capability only requires effort from the company that is required to comply with regulations in a specific market. Therefore, the scores are 2 for all three models. This capability is marked with "M" in the type column in Table 12 The Evaluation Results.

4.2 Evaluation Results

Table 12 summarizes the evaluation results as discussed in the previous section.

Table 12 The Evaluation Results

Stakeholders	Required Capabilities	Type	Central-ized	Semi-centralized	Distributed
Manufacturer, Distributor and Dispenser	Disclose the information based the information requester's privacy access level	A	2	3	1
	Grade the privacy level of the submitted information	A	2	3	1
	Make serialization data available to verify the authenticity of the drug when the drug is shipped	W/S	4	4	3
	Make sure the verification interface is not compromised (e.g. hacked by fake dealers so that fake drugs can be verified as authentic ones)	W/S	4	4	3
	Map serial number to pallet/case number	R	5	5	4
	Map serial number to the storage space/retail branch	R	5	5	4
	Provide transaction information when transferring ownership	W/S	4	4	3
	Record investigation history	W/S	4	4	3
	Report the serial number of stolen drugs	W/S	4	4	3
	Retrieve the aggregated inventory data	W/S	4	4	3
	Secure the system so that the data is not easily hacked and	W/S	4	4	3

	stolen				
	Share unit level information upon request	R	5	5	4
	Support modulation technologies for an easy adaption to international compliance	M	2	2	2
	Share transaction information in a timely manner upon request	R	5	5	4
	Verify if the receiving drugs are stolen ones	R	5	5	4
	Verify the authenticity of the drug according to its serial number	R	5	5	4
	Verify the integrity of transaction information before taking over the ownership	R	5	5	4
Manufacturer and Distributor	Map serial number to receiving dispenser	R	5	5	4
Manufacturer	Map production lot number to serial number	R	5	5	4
	Map serial number to receiving distributor	R	5	5	4
Recall Processing Company	Map serial number to the returning company	R	5	5	4
	Map serial number to pallet/case number	R	5	5	4
	Record destroyed serial number	W/S	4	4	3
Third-party Logistics Providers	Notify related stakeholders upon incompliance	A	2	3	1
	Verify the integrity of transaction information before taking over the ownership	R	5	5	4
Regulator	Verify the data consistency of investigated drugs across the supply chain	R	5	5	4
Total Score		1	110	113	85

4.3 Implications of the Scores

The resulting scores represent pros and cons of these three data sharing models. The score of the distributed model is much lower than that of the other two models, mainly due to the lack of its cost-sharing synergy. However, the distributed model has its own advantages. It is the most flexible model to deal with compliance variations. The centralized model is the opposite of the distributed model. It has the best cost-sharing synergy, but the least compliance-variation flexibility. The semi-centralized model is a combination of the centralized and distributed models. Therefore, the semi-centralized model has the benefits of the other two models, which leads to the highest total score for the semi-centralized model.

To further demonstrate the disadvantages of the centralized and distributed models, let's suppose company A is a multinational drug manufacturer with subsidiaries in the US, Europe and South America, and South America undergoes policy changes. In the centralized model, the U.S. and European subsidiaries will be affected by the system updates reflecting the policy changes. In the distributed model, the company has to build the system from scratch for all of its subsidiaries without any cost sharing benefits.

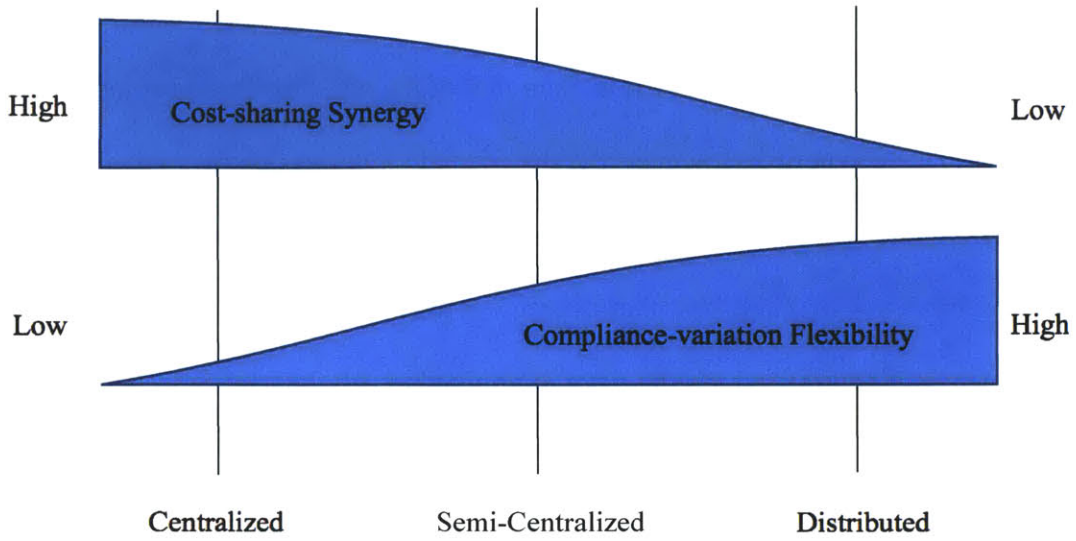

Figure 6 Pros and Cons of the Three Data Sharing Models

5 Discussion

5.1 Recommendations

Based on the evaluation scores, we recommend the semi-centralized model for compliance with the DSCSA, because it provides a balanced mix of compliance-variation flexibility and cost-sharing synergy.

The centralized model is slightly less desirable than the semi-centralized model, because of more difficult coordination in scenarios that require collaboration. A semi-centralized data exchange model is usually built around drugs that are distributed in similar supply chain models, which are either from the same manufacturer or sold by the same distributor or dispenser. The similarity of the drugs makes it easier to negotiate between the different stakeholders that are involved in the model.

The distributed model is less favorable compared to the other two models, since it has the least cost-sharing synergy. The upfront cost to set up the software system required by

compliance with the DSCSA cannot be shared among related entities. Each company has to build and maintain its own system separately.

5.2 Limitations and Potential Improvements

The COSPI scorecard methodology as developed in this research has the following limitations, which can be resolved within the framework:

1. Cost analysis is qualitative not quantitative.

   The values of the scores are indicators of the relative favorability of the models. These values are not necessarily proportional to the actual costs. What's more, individual scores do not have any meaning by themselves. Collecting real cost data may increase the accuracy of the scoring, but the challenge is how to decide upon a common value that represents different cost estimates by different companies for the same effort.

2. The scoring scale is arbitrarily decided.

   The current one-to-five scale is an extreme simplification of a complex problem. It makes sense in the current model since we are using a qualitative analysis. However, a scale with more sensitive divisions is needed if quantitative analysis is to be employed.

3. Different criteria use the same weight.

   Currently, we assume the same weight across all of the capabilities. However, different capabilities may be of different importance to stakeholders. As a result, the relative importance of the capabilities is not accurately reflected in this scoring system. This limitation can be overcome by adding different weights to the capabilities in the current system.

These limitations lessen the accuracy of this framework, but they do not affect the ability of the framework to guide qualitative decisions. Future research could improve on this by fixing the above three limitations.

6 Conclusions

6.1 Findings and Insights

The United States has one of the safest drug supply chains in the world. However, its security is threatened by new challenges such as counterfeit, diverted, and illegally imported drugs. To counter the new challenges, the Drug Supply Chain Security Act (DSCSA) was signed into law by President Obama on November 27, 2013, with a 10-year implementation timeframe. As a result, companies in the U.S. pharmaceutical industry, including drug manufacturers, distributors, and dispensers, are challenged to fully comply with the DSCSA by 2023.

Compliance with the DSCSA will enable companies to operate and manage the risks in their supply chains more efficiently. Industry consortiums, such as the Healthcare Distribution Management Association (HDMA), and the industry leaders have recommended various interoperable data exchange models for the implementation of compliance. However, domestic and international complexities make it difficult to pick the optimal model for the industry.

We started with categorizing the known data exchange models that can be potentially used by the U.S. pharmaceutical industry and obtained three categories: the centralized, semi-centralized, and distributed data exchange models. Next, we developed a scorecard methodology, called the COSPI scorecard, based on the SC2020 framework that considers various factors across the entire supply chain. Finally, we examined the categorized models using this scorecard methodology and reached our final conclusion: the semi-centralized model provides a balanced mix of compliance-variation flexibility and cost-sharing synergy. Based on these findings, we

recommend the U.S. pharmaceutical industry to use the semi-centralized model for DSCSA compliance.

6.2 Future Research

Although they do not change the framework's ability to guide the decision, multiple improvements can be applied to this framework for better accuracy. First, the scoring accuracy can be improved by incorporating a quantitative analysis of the real cost data. This would add more granularity to the evaluation framework. Second, with enhanced granularity, a scale with more sensitive divisions should be introduced to better represent the increased complexities. Third, a weight system can be incorporated to the framework to reflect the relative importance of different criteria. Since different stakeholders may have different definitions of the relative importance, a consensus about weights has to be reached before the weighted framework is used to guide decisions for the industry.

This framework was developed to evaluate different types of interoperable data sharing models, but the methodology behind it can be used in other supply chain scenarios where decisions are made based on multiple dimensions and among multiple stakeholders.

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