The Optimal Solution

DSCSA Pilot Project Industry Conclusions

Prepared For

March 2020

Executive Summary

The Drug Supply Chain Security Act (DSCSA) enacted in November 2013, provided a set of phased requirements that were designed to result in “secure, interoperable product tracing at the package level in order to enhance drug distribution security and further protect the public health…” by 2023.

Since that time, the industry and solution providers have worked diligently to meet the various milestones provided in the DSCSA. As the DSCSA in itself is not very prescriptive, a great deal of collaboration was required between supply chain participants and with solution providers to effect solutions that allowed each group of supply chain participants (manufacturers, wholesale distributors, dispensers, and re-packagers) to meet their respective deadlines.

The collaboration among trading partners, has resulted in the necessary adoption of GS1 as the defacto standard for identifying products and trading partner locations, encoding barcodes and exchanging serialized data. It also highlighted the fact that individual product packages are physically packed into shipping cases and shipping cases are placed onto pallets to facilitate the efficient movement of products through the supply chain. And knowledge about what happens to a particular package of product when the case containing that package is shipped, requires some knowledge of the relationship shipping case and the packages it contains – a process we refer to as aggregation and inference. We also learned that standards, while immensely helpful to getting us where we are today, are flexible enough that they may be implemented differently among solution providers such that fairly extensive data mapping is required when exchanging information between trading partners.

We have seen trading partners and solution providers take different approaches to meeting the requirements set forth in the DSCSA. For example, some manufacturers or their trading partners, recognizing that transaction information would eventually need to be exchanged in a secure, interoperable, electronic manner, opted to implement solutions that supported aggregation from the start. Some manufacturers, either because of cost or lack of a requirement to do so, have chosen to serialize but not aggregate. Larger wholesalers who have a business need to resell returned products, have integrated the verification of product identifiers into their business processes and have implemented the systems to support that verification process. Some smaller wholesalers have decided that the business benefit of being able to resell returned products is not worth the investment of systems to support automated verification. The same is true of many dispensers.

Recognizing that the supply chain has taken different approaches to complying with the requirements set forth in the DSCSA, new technologies have emerged with the promise of allowing supply chain partners to meet their verification obligations under the DSCSA taking into account the fragmented approach to aggregation. The verification router service (VRS) uses a directory-based service that directs a verification request from the requester to the manufacturer (responder) and returns a verification response to the requester.

The DSCSA aims to enhance drug distribution security and further protect the public health through the adoption of secure, interoperable product tracing at the package level. The Optimal Solution views the problem of enhanced drug distribution security through a wider lens. While we understand the need to be able to investigate the supply chain breeches – something that could certainly be accomplished by reviewing the movement of a package through the supply

chain – we believe the public health is far better served by preventing those breeches in the first place. At the same time, given broad concern over the escalation in healthcare costs, we believe it imprudent not to examine the ways enhanced visibility of drug supply data can be used to bring value by reducing those costs.

As pointed out above, the industry has been somewhat fragmented in its approach to meeting the requirements of the DSCSA and there are still questions around where drug supply chain data should live and the underlying technology (blockchain etc.) that will be used to facilitate the exchange of data. However, the underlying premise has not changed, that the electronic exchange of transaction information between trading partners must occur in a secure interoperable manner for each transaction going back to the manufacturer.

While it is clear that GS1 standards are here to stay, the exchange of data could be better facilitated, and therefore costs reduced, if the industry and their solution providers could coalesce around a common set of canonicals for data exchange. At the same time, if GS1 is going to be the standard by which data is exchanged, and since a key component of the standard is the Global Location Number (GLN) which identifies trading partner information, it is important that all supply chain participants, regardless of their role have a GLN. And if the objective is to track the physical movement of product through the supply chain, that physical product movement must be replicated in the supply chain data through the point at which the product leaves the supply chain - either dispensed or destroyed.

How electronic data is exchanged, where it is stored, and the underlying technology by which it is exchanged is less important to the Optimal Solution than that the data actually exists. Assuming that electronic exchange and storage of transaction information occurs, the Optimal Solution presents a solution which cannot only detect bad actors trying to introduce illegitimate products into the supply chain but can prevent that product from moving through the supply chain. The Optimal Solution also demonstrates, through the use of available technologies how to increase the robustness of supply chain data, and convert that data into information, to further the goal of protecting the public health and reducing supply chain costs.

The Optimal Solution is a synergistic team composed of data and analytic experts, Internet of Things (IoT) experts as well as serialization and supply chain experts. The team recognized early on that no single vendor solution provider has the functional breadth and technical expertise to solve the Interoperable DSCSA challenge and extract value from supply chain data. At best the industry would end up with a host of point solutions that solve a particular piece of the supply chain puzzle with no way to aggregate disparate data sources and convert that data into meaningful information. Recognizing that solution providers are businesses, and can never be all things to all people, the team took a more top down approach by asking what kinds of problems could we solve if we had better supply chain information? What kinds of data would we need to support that information? We then looked at what technologies would be needed to gather that data, and finally what technologies would be necessary to gather data from disparate data sources and convert that data into meaningful information.

At the same time, we recognized that there would be hurdles to overcome for such a solution to gain wide acceptance:

- The system would need to meet regulatory and legal requirements
- The system would have to operate in near real-time
- The system would have to deliver value by increasing benefit and/or reducing costs
- The system would need to meet the needs of thousands of supply chain participants
- The system would need to be accepted by thousands of organizations
- The system would need to work with different technologies including multiple blockchains
- The system would need to address data privacy and governance issues
- The system would need to be scalable with the ability to handle millions of transactions and potentially trillions of serial numbers
- The system would need to leverage the GS1 system of standards

The proposed solution developed by the team comprises a technical architecture that addresses these constraints and is called the Serialized Distributed Extensible Service (SDxS). The remainder of this document provides an overview of Drug Supply Chain operations in the context of DSCSA. In addition to new technical innovations that not only improve the safety and security of the Drug Supply chain but provide enhancements to overall life science and healthcare industries. We will specifically be highlighting innovations related to:

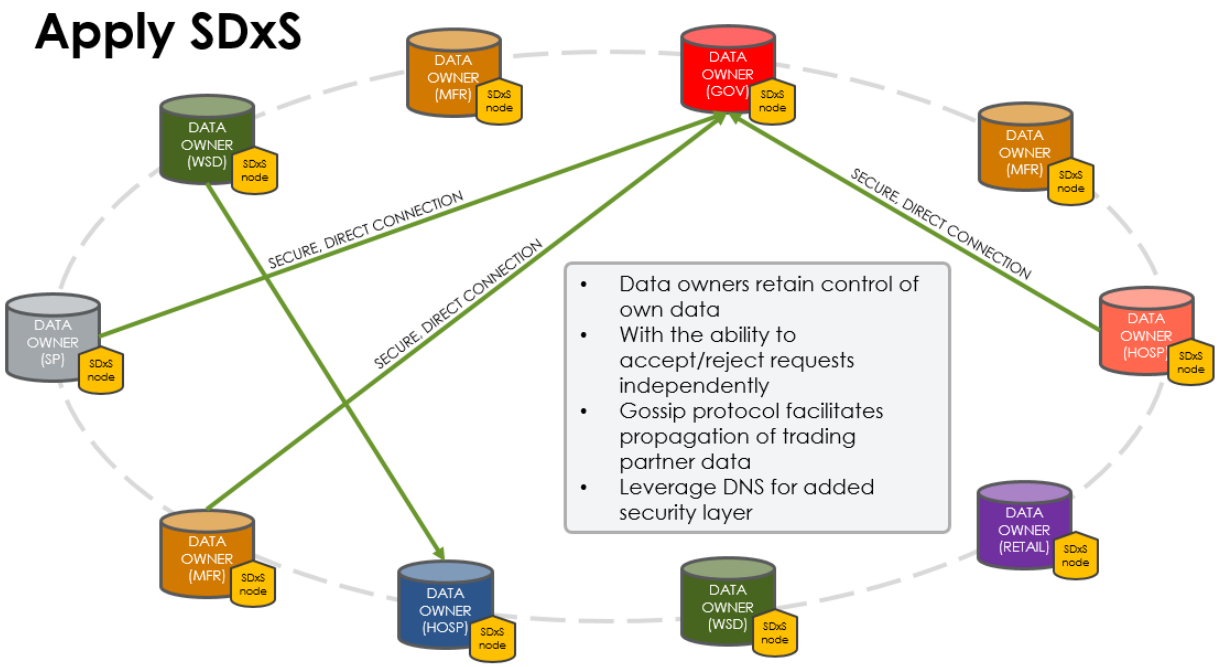
- Trusted Labels – eFingerprinting
- IOT - Supply Chain Visibility in Transit
- Blockchain - Distributed Ledger Technology
- Analytics and Machine Learning - Anomaly detection and value beyond compliance
- Mobile Apps - Geo fencing and Access

Introduction

The Optimal Solution Pilot team defines 'interoperability', in the context of the FDA's DSCSA regulations, as the ability for disparate systems and technologies to safely, securely, and effectively transmit and receive data amongst independent industry trade organizations. The organizations that will actively participate in the system are anticipated to be industry trading partners with uniquely diverse views of the supply chain. In aggregate, the whole of the data is undoubtedly sensitive and must not be accessible to unauthorized parties.

It is worth taking a moment to reflect on the Optimal Solution Pilot team's efforts and how we arrived at the recommendation we are proposing in this blueprint. Our team consists primarily of industry solutions provider companies where value is added in the handling, transmission, and processing of data and producing business insights. Solutions providers play an important part in the drug supply chain while not ever coming into possession of drug product. As solutions providers, our team adds unique perspectives on the challenges that surround handling and transmission of data.

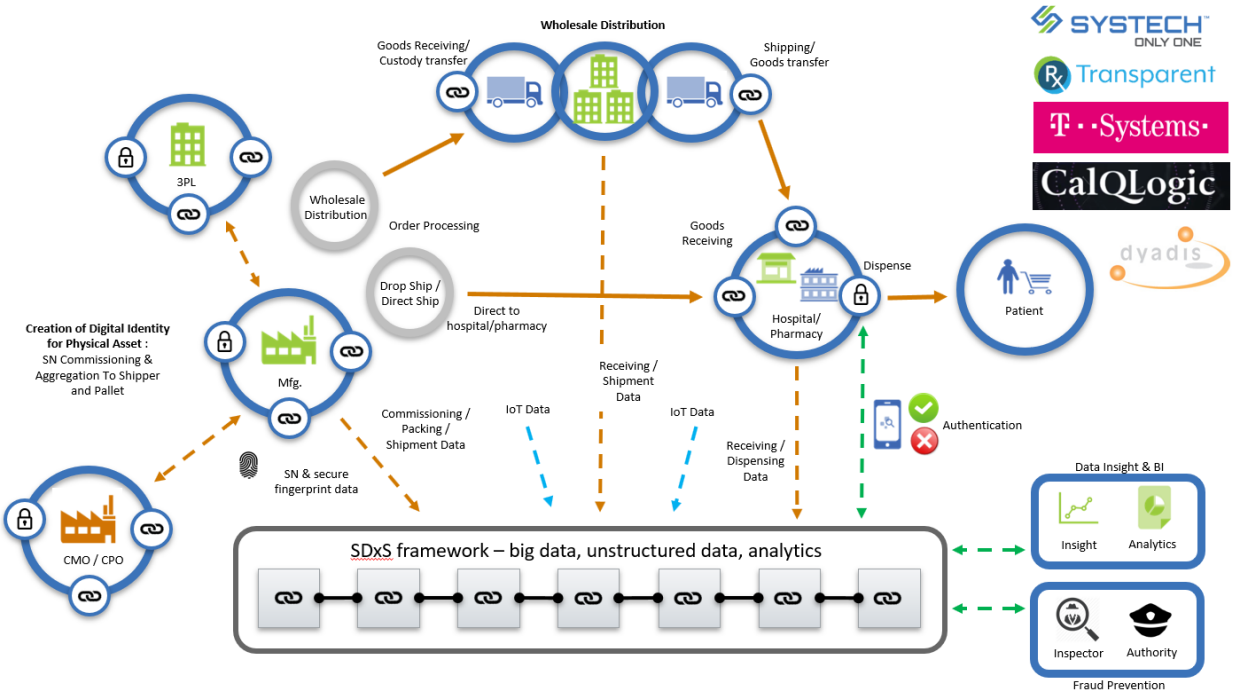
The Optimal Solution Pilot team was initially working to determine how to apply blockchain technologies to solve the challenges at hand. We put a lot of focus on data privacy and security, as well as consensus compute performance, storage, and scaling around a blockchain-based solution. After many iterations going back and forth on which consensus algorithms to use and what to store on-chain, we came to the realization that the expansion of transaction volumes (when the FDA requirement moves to including product identifiers in transaction information) would eventually not be as cheap as expected for node operators, and the overall cost of an interoperable drug supply chain. It was at this time that we, as a team, took a step back to reflect on the approach we had taken and decided to re-frame our solution with existing technologies while maintaining the key benefits of a blockchain-based solution.



Given the sensitive nature of the data that is to be transmitted as a part of the FDA's DSCSA legislation, the security of the data has become one of the chief concerns amongst the prospective participants of the interoperable system. The team has taken these concerns and constraints into careful consideration and has created the following proposed framework we are calling Serialized Distributed Extensibility Services, or SDxS, to be used for a viable solution towards creating a secure interoperable system by which trading partners and organizations can exchange data.

Drug Supply Chain Operations

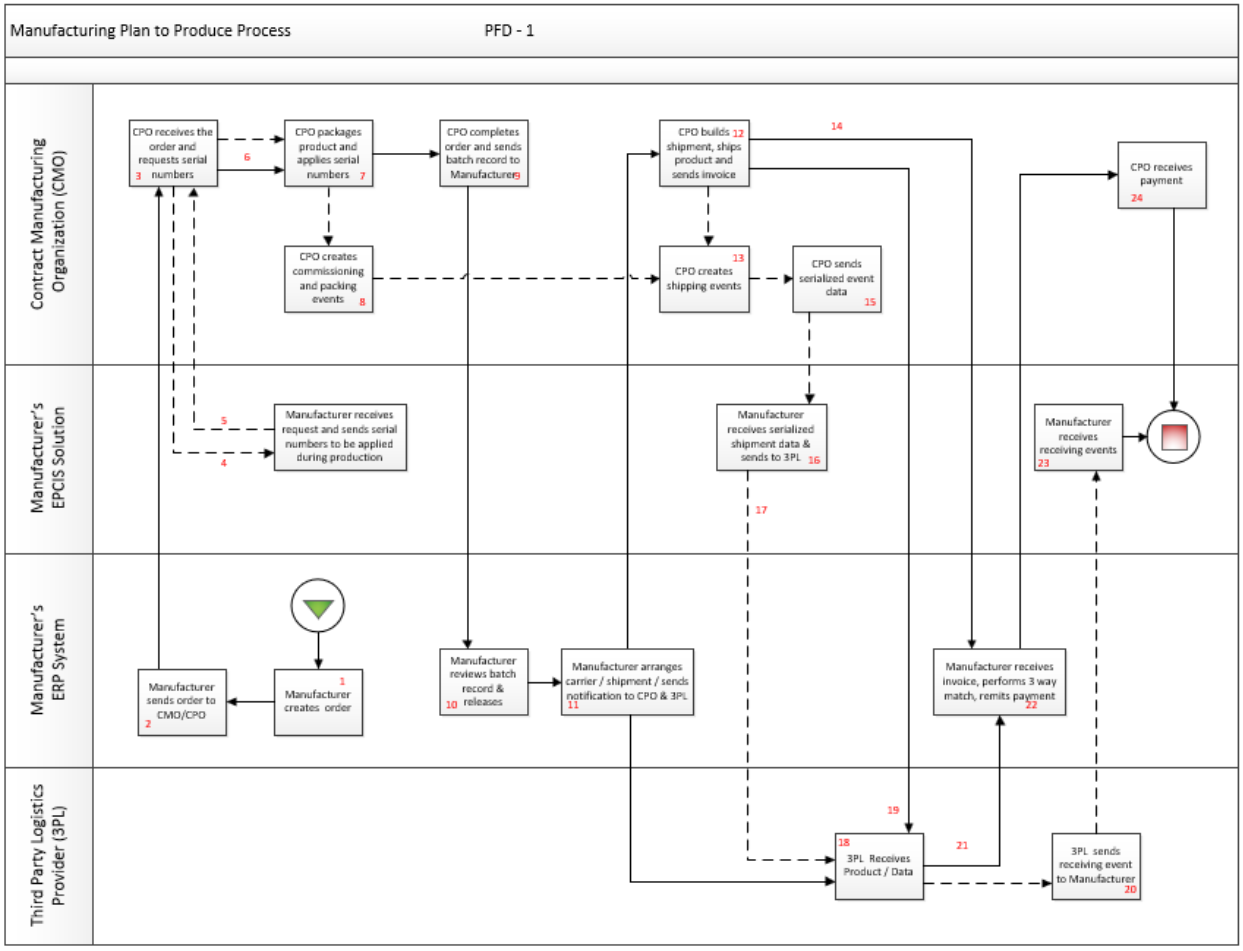
Below is a high-level overview of the Drug Supply Chain. Using this model we will look at the types of EPCIS data that we expect to be exchanged between supply chain participants, then overlay the SDxS framework over that data model and illustrate examples of how the SDxS framework can be used to secure the drug supply chain, with the ultimate intention to drive value from the supply chain either by increasing benefit or reducing costs.



The SDxS uses a set of technologies to connect disparate structured and unstructured data sources. Using advanced analytics techniques queries can be executed across these different data sources to provide meaningful business intelligence

DSCSA Manufacturer Packaging Process

The packaging process involves the packaging of drug product into finished goods either in house or at a contract manufacturing organization and getting those finished goods to a manufacturer's distribution center or third-party logistics provider.



The diagram above illustrates a plan to produce process flow for a typical manufacturer. In this example we utilize a contract manufacturing organization (CMO) for packaging and a third-party logistics provider (3PL) for distribution. While we realize not all products are produced a CMOs and not all products are distributed through 3PLs, the example serves to help illustrate that for a system to be interoperable, product movement through the supply chain needs to be reflected in the data documenting that product movement especially when product moves between unrelated entities.

In the example above, a packaging order is placed on a CMO by a manufacturer. The CMO requests and the manufacturer sends the serial numbers that the CMO will apply to each level of product packaging.

As serial numbers are applied to sales units, commissioning events are created. As sales units are packed into cases, a serial number for the case is commissioned and the relationship between the case serial number and the serial numbers of the sales units contained within the case are electronically documented in a packing (aggregation) event.

At the same time packaging at the sales unit level is taking place, Internet of Things (IoT) internet enabled tags may also be attached to the package and associated with the package serial number. These devices, not much larger than a postage stamp, are capable of providing real time information such as GPS position, temperature, light exposure etc. With a current battery life of up to 5 years, the tags can easily last the life of the product. While these tags are particularly useful in tracking products through the supply chain, they also offer complete visibility of product during the "last mile" or when product enters and moves through a large facility such as a hospital. As will be discussed later, this has the potential for huge benefits, in terms of reducing working capital, and managing excess, obsolete and expiring inventory.

As shipping cases are packed into shipping containers (pallets), a serial shipping container code (SSCC) for the shipping container/pallet commissioned and the relationship between the SSCC representing the shipping container/pallet and the shipping cases placed on the pallet are electronically documented in another packing (aggregation) event.

If there are intermediate levels of packaging (bundles, trays, boxes) between the sales unit and the shipping case, each intermediate unit of packaging is assigned a serial number, that serial number is commissioned, and packing events are created to document the relationship between the serial number of the intermediate package and the serial numbers of the sales units contained within. Similarly, as intermediate packaging units are packed into cases, packing events are created to document the relationship of the case serial number to the serial numbers of the intermediate packaging units contained within the case.

Once packaging has been completed, the manufacturer will have a record of:

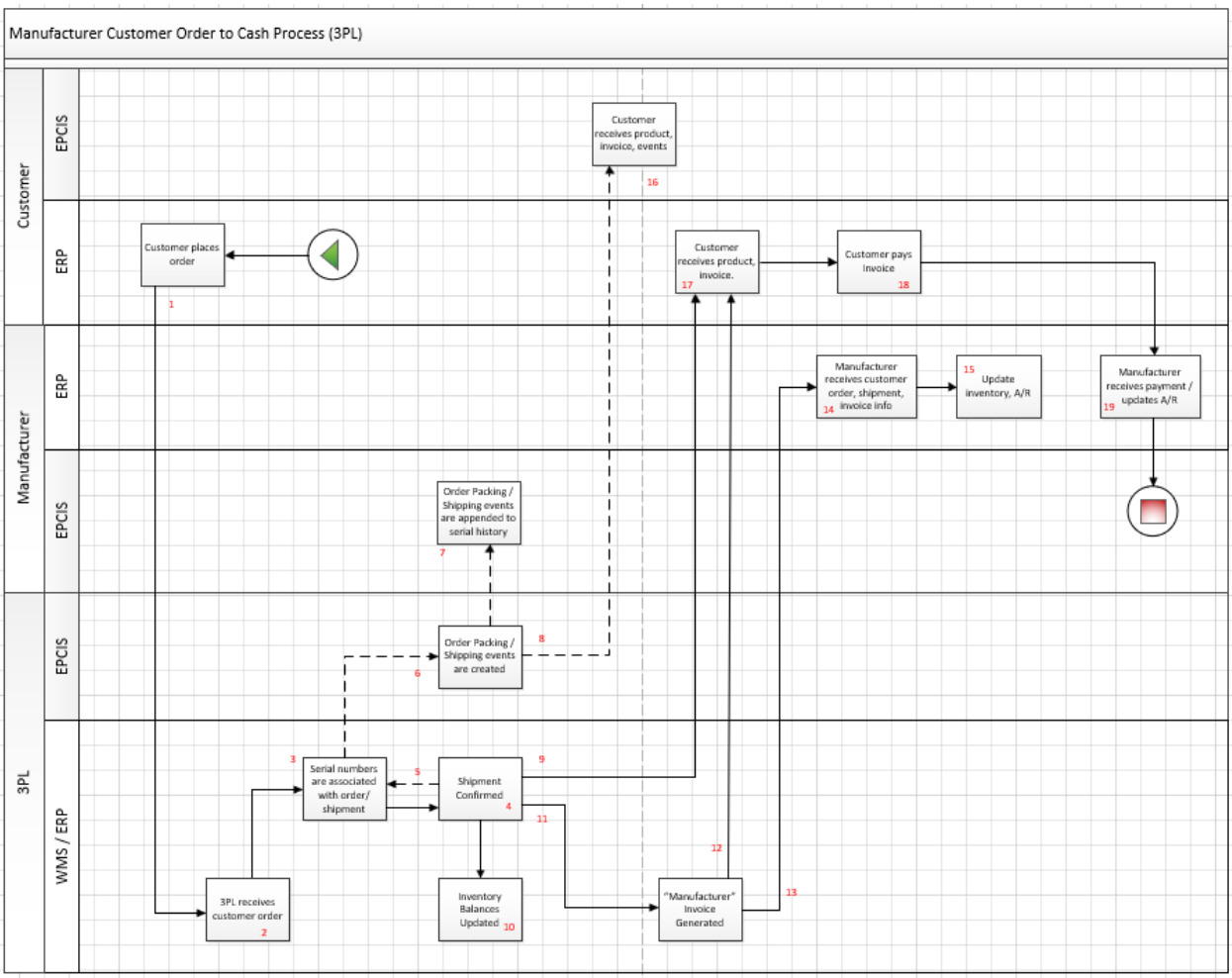
Packaging Data
Commissioning Events
sales units
shipping cases
SSCCs
Packing Events
sales units to shipping cases
shipping cases to SSCCs
Additional Information
lot number
expiration date
internet tag id (if used)

If packaging was performed at a CMO, this information will be sent to the manufacturer from the CMO. If the manufacturer distributes using a third-party logistics (3PL) provider, the manufacturer will transmit this information along with a shipping event to the 3PL to support the manufacturer's order to cash process. Upon receipt of the shipment the 3PL will generate a receiving event.

In the case of high value / temperature sensitive products, or supply chains that are longer than a couple of days, shipments of product to a distribution center may be actively monitored using an IoT device to provide near real time data around GPS position, or excursions around key parameters.

DSCSA Manufacturer Order to Cash Process

The manufacturer's order to cash process involves fulfilling customer orders from the manufacturer's distribution center. Customers could be wholesalers, distributors or direct ship customers such as hospitals.



The diagram above illustrates a typical order to cash process for a manufacturer fulfilling a customer order – a wholesaler for example.

As products are picked in the distribution center, the serial numbers of the sales units and shipping cases picked are associated with an SSCC that is associated with the customer order. Because there was a packing event created during packaging that created an association between the serial number of a shipping case and the serial numbers of the sales units within the shipping case – the sales unit serial numbers within full cases used to fulfil the customer order are known.

At the time the customer order is shipped to the wholesaler a record of the shipment is created and sent to the wholesaler. This record would contain the customer name, address, global location numbers (GLN) of manufacturer and customer, ship date, order number, shipping container code (SSCC), serial numbers of sales units within the shipping container, serial

numbers of shipping cases within the shipping container, packing events describing the serial numbers of the sales units contained within a shipping case, lot number and expiration date.

Other traditional order information such a product, quantities, price etc. are captured in the manufacturer's ERP system.

Once shipping has occurred, the manufacturer will have a record of:

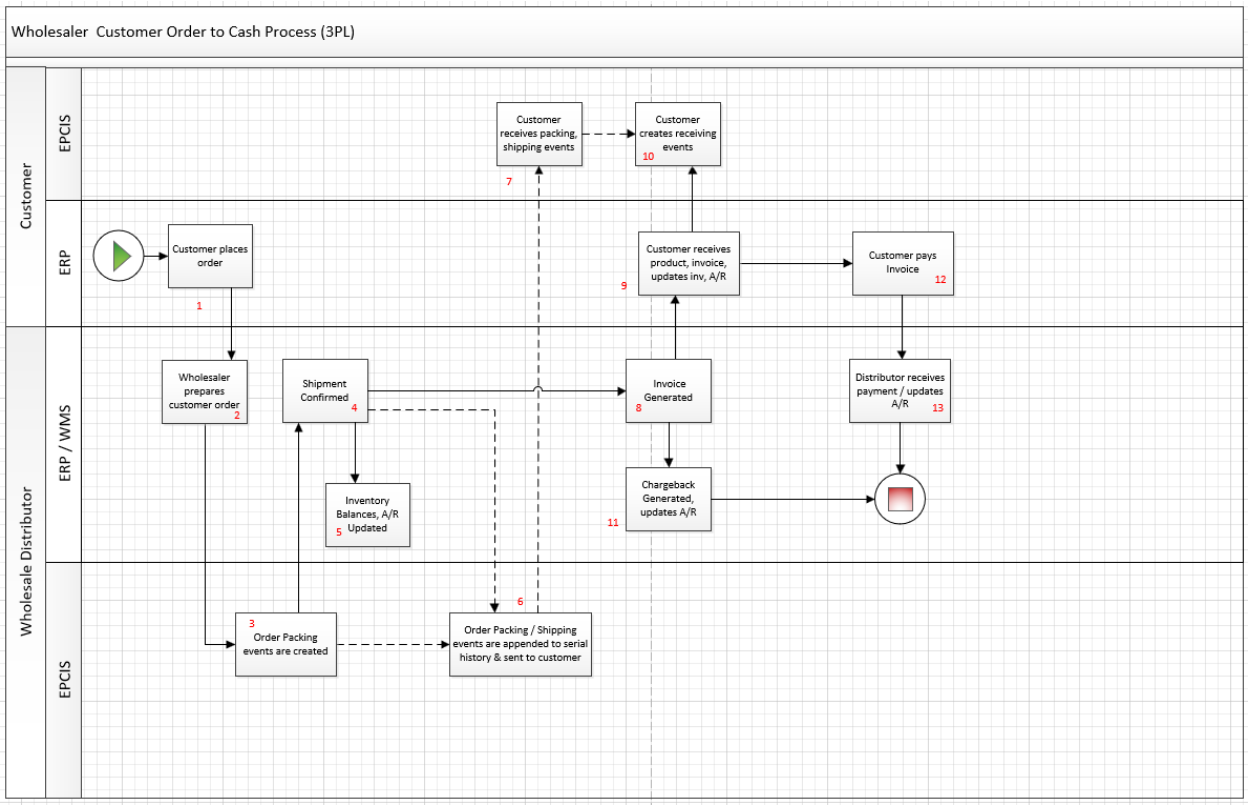
Shipment Data
Shipping Event
GLNs (from & to)
Commissioning Events
SSCC
Packing Events
sales units to SSCC
shipping cases to SSCCs
sales units to shipping cases
Additional Information
lot number
expiration date
internet tag id (if used)
order number
products
prices

Upon receipt of the shipment the wholesaler creates a receiving event against the shipment and will have a record of the following:

Receiving Data
Receiving Event
GLNs (from & to)
Commissioning Events
SSCC
Packing Events
sales units to SSCC
shipping cases to SSCCs
sales units to shipping cases
Additional Information
lot number
expiration date
internet tag id (if used)
order number
products
prices

DSCSA Wholesaler Order to Cash Process

The wholesaler's order to cash process involves the fulfillment of customer orders. Customers could be other wholesalers, distributors, hospitals, or pharmacies.



The diagram above illustrates a typical order to cash process for a wholesale distributor fulfilling a customer order – a dispenser for example. This process is not unlike the manufacturer order to cash process.

As products are picked in the wholesaler distribution center, the serial numbers of the sales units and shipping cases picked are associated with an SSCC that is associated with the customer order. Because there was a packing event created during packaging, that was sent to the wholesaler by the manufacturer, the serial numbers of the sales units contained within any full cases used to fulfil the customer order are known.

At the time the customer order is shipped to the dispenser a record of the shipment is created and sent to the dispenser. This record would contain the customer name, address, global location numbers (GLN) of the wholesaler and dispenser, ship date, order number, shipping container code (SSCC), serial numbers of sales units within the shipping container, serial numbers of shipping cases within the shipping container, packing events describing the serial numbers of the sales units contained within a shipping case, lot number and expiration date.

Other traditional order information such a product, quantities, price etc. are captured in the wholesaler's ERP system.

Once shipping to the dispenser has occurred, the wholesaler will have a record of:

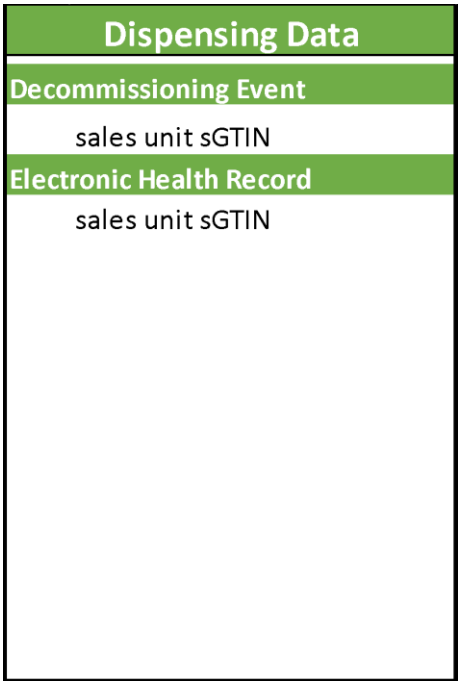
Shipment Data
Shipping Event
GLNs (from & to)
Commissioning Events
SSCC
Packing Events
sales units to SSCC
shipping cases to SSCCs
sales units to shipping cases
Additional Information
lot number
expiration date
internet tag id (if used)
order number
products
contract number & price

Upon receipt of the shipment from the wholesaler, the dispenser creates a receiving event against the shipment and will have a record of the following:

Receiving Data
Receiving Event
GLNs (from & to)
Commissioning Events
SSCC
Packing Events
sales units to SSCC
shipping cases to SSCCs
sales units to shipping cases
Additional Information
lot number
expiration date
internet tag id (if used)
order number
products
contract number & price

DSCSA Dispensing Event

Upon dispensing an event is created that indicates that the serial number for the sales unit has been decommissioned as dispensed and has effectively been removed from the supply chain:



DSCSA Returns, Reverse Distribution

From a supply chain perspective, it is important that all movement of product between trading partners is reflected in the supply chain data until that product is removed from the supply chain. Removal of physical product from the supply chain should be accompanied by a dispensing event, destruction event or some other event that reflects the products removal from the supply chain in the data. Otherwise, the supply chain data will provide an inaccurate representation of physical product in the supply chain making the data much less useful in performing recalls and analyzing drug shortages etc.

As you can see from the previous sections the US drug supply chain is complex. In supporting the DSCSA all serialized data must not only be stored but easily identified by FDA and between the participants of the supply chain. Our approach to handling data, identifying counterfeit product and meeting the 'interoperability' aspects of the DSCSA is described below. At the same time, we will examine how increased data visibility across the supply chain can be leveraged to provide value by increasing benefit or reducing costs.

While the DSCSA does not specify a standard for the exchange and storage of manufacturing lot data including serialized, aggregated packaging data, the industry has coalesced around using GS1 data and messaging standards. The product tracing requirements of DSCSA as well as the real time data needs of the supply chain will require that trading partners exchange

serialized data between trading partners and the consensus again is to use GS1 EPCIS Messaging to perform this task. The removal of the transaction history (TH) requirement in 2023 does not alleviate the requirement for trading partners to share Transaction Information and Transaction Statements with trading partners in conjunction with each change of product ownership.

As such there are several solution providers that can process and store inbound and outbound supply chain data from the point of manufacture to the point of dispensation.

Proposed Technical Solution SDxS

Introduction

At this point in the FDA's search for an interoperable solution many companies have made investments in their own solutions. Any solution proposed should be both technically sound and low cost which will drive adoption of the DSCSA across the industry when fully implemented in 2023. The Optimal Solution Pilot team defines 'interoperability', in the context of the FDA's DSCSA regulations, as the ability for disparate systems and technologies to safely, securely, and effectively transmit and receive data amongst independent industry trade organizations. The organizations that will actively participate in the system are anticipated to be industry trading partners with uniquely diverse views of the supply chain. In aggregate, the whole of the data is undoubtedly sensitive and must not be accessible to unauthorized parties.

It is worth taking a moment to reflect on the Optimal Solution Pilot team's efforts and how we arrived at the recommendation we are proposing in this blueprint. Our team primarily comprises industry solutions provider companies where value is added in the handling, transmission, and processing of data and producing business insights. Solutions providers play an important part in the drug supply chain while not ever coming into actual possession of drug product. As solutions providers, our team adds unique perspectives on the challenges that surround handling and transmission of data.

The Optimal Solution Team designed the SDxS architecture to meet the Interoperability requirements of the Drug Supply Chain Security Act. It was not designed as a replacement for the 2019 Verification Routing Services (VRS) developed to support serialized returns.

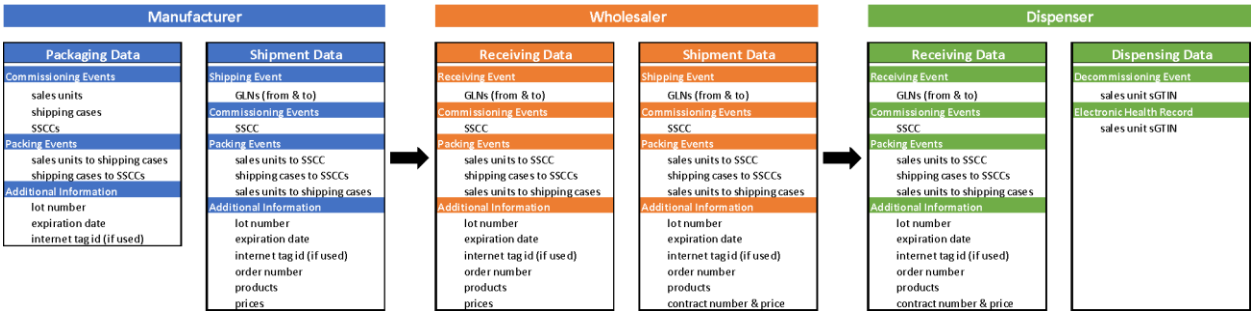
The Optimal Solution Pilot team was initially working to solve how to apply blockchain technologies to solve the challenges at hand. We put a lot of focus on data privacy and security as well as consensus compute performance, storage, and scaling around a blockchain-based solution. After many iterations going back and forth on which consensus algorithms to use and what to store on-chain, we came to the realization that the expansion of transaction volumes, when the FDA requirement moves to serial numbers, would eventually be prohibitively costly for node operators in general. It was at this time that we, as a team, took a step back to reflect on the approach we had taken and decided to re-frame our solution with existing technologies while maintaining the key benefits of a blockchain-based solution.

Given the sensitive nature of the data that is to be transmitted as a part of the FDA's DSCSA legislation, the security of the data has become one of the chief concerns amongst the prospective participants of the interoperable system. The Optimal Solution Pilot team has taken

these concerns and constraints into careful consideration and has created the following proposed framework we are calling **Serialized Distributed Extensibility Services**, or **SDxS**, to be used for a viable solution towards creating a secure interoperable system by which trading partners and organizations can exchange data.

Overview

In the previous section we reviewed some typical supply chain transactions involving the movement of product through the supply chain from the point of packaging through the point of dispensation. We also looked at the types of data that would be required to represent the physical flow of serialized product through the supply chain from the point of packaging through the point of dispensation.



The Serialized Distributed Extensibility Services (SDxS) framework is envisioned as open-source in order to facilitate data exchange over the internet via a secure, distributed, decentralized broadcast or direct connection. Any resource that participates in the exchange of data serves as a node on the network. Because data owners retain control of their own data, they are able to accept or reject any requests for that data independently.

In an effort to anticipate and support a wide variety of data request and transmission cases, the SDxS specification deliberately allows for multiple mechanisms to send requests and receive responses across the network; broadcast request, broadcast response, channel request, channel response, direct request, and direct response.

A broadcast request is an encrypted communication mechanism used to produce a durable request message that will be transmitted via gossip protocol to all of the SDxS nodes on the network. Similar to a durable message queue the message is committed to a storage for processing. The responding trade organization may elect to utilize the broadcast response or direct response method when replying. A Gossip protocol is a process of computer peer-to-peer communication to ensure that data (in this case a request) is disseminated to all members of a group.

A broadcast response is an encrypted communication mechanism used to send an asynchronous response message that will be transmitted via Gossip protocol to all of the SDxS nodes on the network.

A channel request is an encrypted communication mechanism used to broadcast a request to a group of verified trade organizations via direct connections to multiple SDxS nodes.

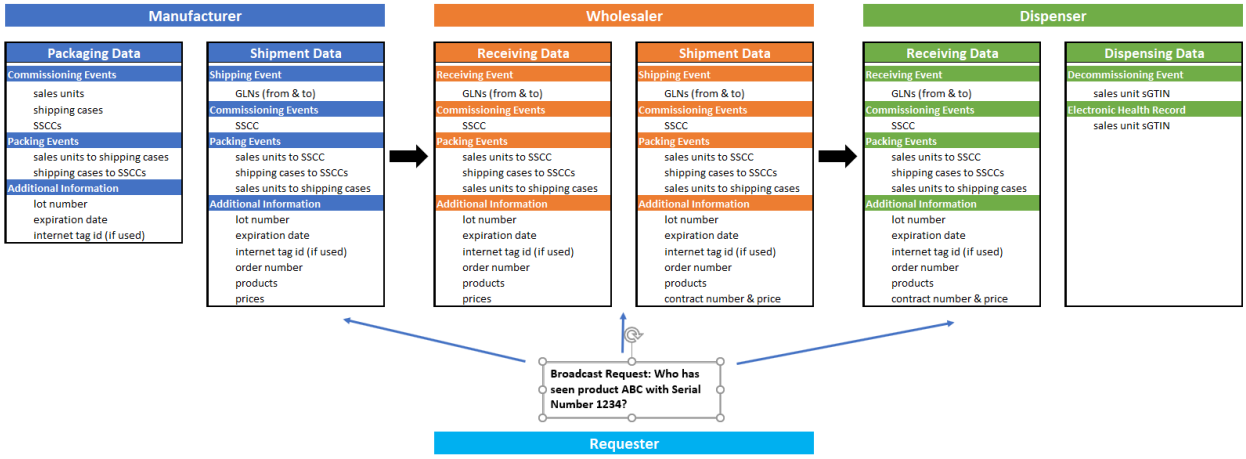
A channel response is an encrypted communication mechanism used to send an asynchronous response to a group of verified trade organizations via direct connections to multiple SDxS nodes. The responding trade organization may elect to utilize the channel response or direct response method when replying.

A direct request is an encrypted communication mechanism used to send a request to a verified trade organization via a direct connection to an SDxS node.

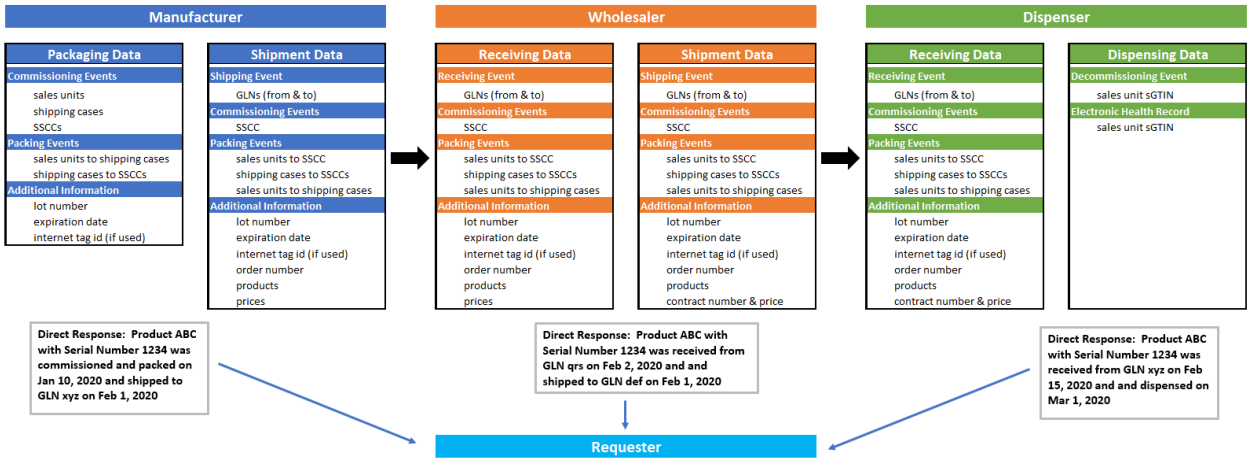
A direct response is an encrypted communication mechanism used to send an asynchronous response to a verified requestor via a direct connection to an SDxS node.

Before going into the technical details of the SDxS solution let us look at a simple example of how the SDxS could support the tracing requirement set forth in the DSCSA.

In the example below, a requestor, the FDA for example, might want to know the path a particular serialized product took through the supply chain and where that product is located at the time of the request. The requestor could send a broadcast request requesting any serialization events for that serialized product. The broadcast request would be disseminated to all the nodes on the supply chain network:



Trading partners with information regarding that particular serialized product could be configured to return a direct response that includes the relevant EPCIS events:



While the example above illustrates how the SDxS framework can meet the traceability requirements set forth in the DSCSA, the SDxS framework could be configured to monitor the supply chain network to potentially identify products entering the supply chain illegitimately.

For example, exception conditions could be generated when a shipment from a wholesaler occurs without a corresponding receiving event or when a dispensing event occurs at a dispenser without a corresponding receiving event. Such an exception condition might trigger an investigation into all the events associated with that product serial number combination to verify that the product was actually shipped to the party in question.

Design Considerations

The following constraints and challenges are the primary drivers behind the Optimal Solution Pilot team's motivations for the SDxS architectural design. These constraints were identified by the team early in the design process and helped to shape the solution described in this publication.

○ Business Constraints

Business constraints and challenges range from regulatory, political, industrial, and organizational topics including costs which we have included as a separate section. In the context of the interoperable system, we have organized these matters to state this team's motivations in producing a design architecture that results in a more favorable outcome for each constraint.

○ Regulatory

There are many aspects of the DSCSA regulatory framework that are time-bound. One of those is the 2023 deadline requirement of the interoperable system. All transaction records exchanged between trade organizations today utilize an FDA-prescribed format where three components of the report are required to be present; transaction information, transaction history, and transaction statement.

Today, product tracing history, as found in the transaction history component, is required as a part of the tracing data payload as drug product moves through the supply chain. Trading partners are not to accept drug products unless there is historical tracing data transmitted with

it. The industry has, in large part, standardized this exchange format with X12, EDI, and EPCIS over SFTP or AS2 connections.

In 2023, the transaction report anatomy requirements are due to change. Product tracing history will no longer be required with the implication that the transaction payload could see a modest reduction in size. It is imperative that the solution our team designs be as flexible as possible and to anticipate compatibility with current stated requirements as well as anticipate possible unstated future requirements. Ideally, the recommended solution would also modernize transmission formats as well as security of the connection protocol to safeguard against obsolescence as is the case with the current state of data exchange formats and protocols.

- **Counterparties**

At the time of this publication, we estimate the US drug supply chain industry landscape to be comprised as follows:

- Less than one thousand manufacturing organizations

- Hundreds of manufacturing sites including contract manufacturers

- Less than five hundred licensed wholesale distributors

- Hundreds of thousands of distribution points where drug product is dispensed

Given the current drug supply chain landscape as well as its anticipated future growth, it is important that this team's proposal take into account the aspects of industry expansion and contraction as a part of the design considerations. The interoperable system will surely see new members joining, existing members leaving, and some members joining forces in consolidation events. The proposed interoperable system must be able to support these kinds of industry changes and be resilient to unanticipated trading partner events. It is, therefore, the goal of this team to architect a system design that favors malleability over fragility.

- **Participation**

An interoperable system's value strengthens and declines along with the number of active participants. Given the number of counterparties we have identified, it will be a difficult task to secure participation across the industry, especially if there are new technologies to be adopted or a significant expansion of existing technologies to be instantiated. It is the goal of this team to maximize participation in the interoperable solution by minimizing the impact of the requirements our proposed solution will impose.

- **Cost**

In aggregate, billions of dollars have already been spent by countless trade organizations across the industry in an effort to secure the drug supply chain. Areas of focus have included physical hardware such as scanners and specialized printers as well as physical security at manufacturing facilities and points of dispense with drug storage cabinets. In electronic data, perimeter security appliances and new software systems have been introduced that add more granular technical controls over existing data stores. All of which come at significant cost.

In the pharmaceutical supply chain, this is a zero-sum game. Someone along the line is paying for it somewhere and the buck always stops at the consumer. It is the goal of our team to understand our proposal's cost implications in depth, and to minimize the overall cost to

implement the SDxS solution. At the same time we endeavor to look beyond the tracing requirements set forth in the DSCSA to understand how all the data captured to secure the supply chain can be converted into a wealth of information in order to reduce supply chain costs and increase benefits to the consumer.

- **Technical Constraints**

Technical constraints range from technology and protocol standards to data privacy and security concerns. All of these contribute to the shape and scope of the interoperable system design. We have organized these matters to state this team's motivations in producing a design architecture that results in a more favorable outcome for each constraint.

- **Standards**

When it comes to information exchange and communications there are a myriad of technologies to choose from. So many, in fact, that it can often become increasingly difficult to discern the signal from the noise. Today, we have cutting edge distributed ledgers, smart contracts, automated consensus protocols, and zero knowledge proofs that appear to be leading the way for decentralized autonomous networks.

The key to filtering the broad range of features is to separate the wheat from the chaff as one progresses in designing the interoperable system. During the architecting and design phase, our team experienced many missteps and identified a great deal of the pitfalls associated with many of these solutions. The team never lost sight of the goal of building a way to effectively and securely exchange data using known standards. The Optimal Solution Pilot team has met numerous times in an attempt to tackle the issue of technology standards and we believe we have come to a simple, lightweight, scalable solution in our blueprint. Our recommendation assumes a foundation in existing technologies and blends in decentralized and distributed concepts to achieve interoperability while maintaining data privacy and security as well as the performance characteristics of near real-time communication.

- **Performance**

By 2023, the interoperable system and its participants will assume a performance expectation of near real-time request/response. It would be considered unacceptable, given today's technology options, to produce an interoperable system that does not possess the performance profile of contemporary data exchange systems. The Optimal Solution Pilot team is targeting a secure distributed data exchange architecture that is capable of at least five thousand transactions per second with near real-time responsiveness.

- **Transaction Volume**

It is estimated that the US drug supply chain moves roughly four billion drug products annually (by comparison, Visa processes twenty-six billion transactions every year). Several times that number of transaction records are produced, transmitted, and stored as a result of drug product shipments and deliveries. Consequently, each record is appended to and retransmitted as the drug product traverses throughout the drug supply chain ecosystem. We expect the number of transactions to increase to hundreds of billions and possibly trillions in 2023 when traceability requirements move to product serial numbers.

- **Data Privacy & Security**

Security has become one of the chief concerns of the interoperable system among industry participants and trading partners. The Optimal Solution Pilot team has invested a significant portion of time during the design process to thoroughly anticipate potential vulnerabilities in the SDxS architecture. The resulting recommended architecture is a direct result of the Optimal Solution Pilot team's efforts to address security as a robust, holistic platform resilient to malicious actors.

- **Domain Name System (DNS)**

The SDxS network would require the use of X.509 certificates stored in a DNS entry called a PKIX record. This record would allow for the receiving node to verify the requesting node's authenticity and identity.

- **Cryptographic Signatures**

All requests on the SDxS network must be sent with a corresponding signature that verifies the entire request payload.

Transmission Channels

In an effort to anticipate and support a wide variety of data request and transmission cases, the SDxS specification deliberately allows for multiple mechanisms to send requests and receive responses across the network; broadcast request, broadcast response, channel request, channel response, direct request, and direct response.

- **Broadcast Request**

A broadcast request is an encrypted communication mechanism used to produce a durable request message that will be transmitted via gossip protocol to all of the SDxS nodes on the network. Similar to a durable message queue the message is committed to a storage for processing. The responding trade organization may elect to utilize the broadcast response or direct response method when replying.

- **Broadcast Response**

A broadcast response is an encrypted communication mechanism used to send an asynchronous response message that will be transmitted via gossip protocol to all of the SDxS nodes on the network.

- **Channel Request**

A channel request is an encrypted communication mechanism used to broadcast a request to a group of verified trade organizations via direct connections to multiple SDxS nodes.

- **Channel Response**

A channel response is an encrypted communication mechanism used to send an asynchronous response to a group of verified trade organizations via direct connections to multiple SDxS nodes. The responding trade organization may elect to utilize the channel response or direct response method when replying.

- **Direct Request**

A direct request is an encrypted communication mechanism used to send a request to a verified trade organization via a direct connection to an SDxS node.

- **Direct Response**

A direct response is an encrypted communication mechanism used to send an asynchronous response to a verified requestor via a direct connection to an SDxS node.

Node Domains

The SDxS open source software will allow a node operator to define permitted domain names for inbound communications. Inbound requests are cross referenced with this list before allowing further processing. All other incoming requests are rejected by default in the SDxS open source implementation.

domains.config-

```
[
”{domain ex 1}”,
”{domain ex 2}”,
”{domain ex 3}”
]
```

Node Channels

The SDxS open source software will allow a node operator to define channels for outbound communications. Channel communications utilize a gossip protocol to ensure timely delivery of messages to all designated recipients defined in the channels configuration file.

channels.config-

```
{
                                                                    ”{channel name}”:
        [
                ”{domain ex 1}”,
                ”{domain ex 2}”,
                ”{domain ex 3}”
                ]
}
```

Node Request Mapping

In order to facilitate communication with an organization’s internal resources, the SDxS open source software will feature a request pass-through mechanism that the node operator must

configure prior to joining the SDxS network. The configuration file will expect a JSON object definition that expects each object property to correspond to a valid action name.

The following JSON template is provided as an example for defining an action map:

actionmap.config-
{
”transactions”:”http(s)://{host}:{port}/{path}[?{query string}]”,
”recall”:”http(s)://{host}:{port}/{path}[?{query string}]”,
”shortage”:”http(s)://{host}:{port}/{path}[?{query string}]”,
”{custom action name}”:”http(s)://{host}:{port}/{path}[?{query string}]”
}

SDxS Technical Specification

- Gossip Protocol as a means of distributing data
    - A means to communicate with all of the nodes in the network is necessary to ensure consistency of data across the network
    - This protocol is modeled after the Hashgraph’s Gossip protocol where each node is responsible for brokering requests to two peer nodes that have not yet received the payload or do not respond with HTTP 208. This results in a simple but very efficient mechanism to propagate shared data.
    - Gossip protocol complexity estimates
        - Expected worst case request propagation complexity: O(n^2)
            - Expected worst case time complexity: O(n log n)
            - Expected worst computational complexity: O(n log n)
- DNS
    - Every entity that is registered on the network and running nodes must have valid DNS entries to allow for ownership verification and public key retrieval
            - Using DNS allows for the independent control of keys in a decentralized fashion
    - Expected Values
            - sdxs-pkix.{domain.com} IN TXT ”{x.509 certificate}”
            - sdxs-ident.{domain.com} IN TXT ”{Entity ID}”
            - sdxs-callback.{domain.com} IN A {IP Address}
- REST Interface
    - POST /join/
        - Returns:
            - HTTP 202 Accepted - When join is successfully captured
            - HTTP 401 Unauthorized - Auth failures
        - Headers
            - X-SDxS-Ident: {API Key}
            - X-SDxS-Ephemeral: {Current UTC DateTime in ISO format, signed with requestor’s private key}
        - When request is made
            - Guard Checks
                - API Key must be valid
                    - DNS Query of entity domain must
                    - Have matching API Key (ident)
                    - Have valid pkix public key value

                - Ephemeral value must be verified using public key of corresponding Entity in API Key validation step
                - Ephemeral value must fall within plus or minus five minutes of current UTC DateTime
            - All registered nodes are updated via gossip protocol
        - Nodes on network to transmit latest state of shared data over callback channel specified in DNS
    - POST /{broadcast/channel/direct}/
        - Returns:
            - HTTP 200 OK - When message is successfully captured
            - HTTP 500 Server Error - When server error occurs
        - Headers
            - X-SDxS-Action: {Action Name}
            - [Required only for /channel]
              X-SDxS-Channel: {Channel Name}
            - [Required only for /direct]
              X-SDxS-Direct: {Domain Name}
            - X-SDxS-Ident: {API Key}
            - X-SDxS-Ephemeral: {Current UTC DateTime in ISO format, signed with requestor's private key}
        - Body: JSON Payload
        - When request is made
            - Guard Checks
                - API Key must be valid
                    - DNS Query of entity domain must
                        - Have matching API Key (ident)
                        - Have valid pkix public key value
                - Ephemeral value must be verified using public key of corresponding Entity in API Key validation step
                - Ephemeral value must fall within plus or minus five minutes of current UTC DateTime
                - Optional Channel Name must be defined in channels.config
                - Optional Domain Name must have valid SDxS DNS entries
            - All registered nodes are updated via gossip protocol
    - POST /callback/
        - Returns:
            - HTTP 200 OK - When message is successfully captured
            - HTTP 208 Already Reported - When message has already been received
            - HTTP 401 Unauthorized - Auth failures
            - HTTP 500 Server Error - When server error occurs
        - Headers
            - X-SDxS-Action: {Action Name}
            - X-SDxS-Ident: {API Key}
            - X-SDxS-Ephemeral: {Current UTC DateTime in ISO format, signed with requestor's private key}
        - Body: JSON Payload
        - When request is made
            - Guard Checks
                - API Key must be valid

        - DNS Query of entity domain in DB must
            - Have matching API Key (ident)
            - Have valid pkix public key value
    - Ephemeral value must be verified using public key of corresponding Entity in API Key validation step
    - Ephemeral value must fall within plus or minus five minutes of current UTC DateTime
    - Domain of requestor must be permitted in domains.config
    - Action Name must be specified in actionmap.config

SDxS, the Internet of Things (IoT) and Real-Time Analytics/Machine Learning (RAML)

The internet of things (IoT) and Real-Time Analytics / Machine Learning (RAML) are two technologies will play such a significant role in the evolution of the extended supply chain we thought that it was important to call them out in their own right.

At the end of the day the problem of securing the pharmaceutical supply chain is just that – a supply chain problem. The challenge posed by this particular supply chain problem is that it deals with a complex ecosystem that extends beyond the four walls of any one organization. As such information about what is going on in that extended supply chain is based on having visibility to transactions that occur sporadically across a large number of supply chain participants using a multitude of systems. Because DSCSA tracing information is based on transactions and because a significant amount of effort is required to establish the connections between trading partners to pass EPCIS events (transactions) the exchange of EPCIS data is better suited to trading partners who have established relationships. This reduces supply chain flexibility especially for manufacturers who might want to drop ship a customer, in that they would need to establish and test a trading partner connection prior to executing the transaction.

The other shortcoming of exchanging EPCIS data is that the transaction must be continuously monitored. If not monitored, failures may go undetected until the receiving party tries to access the data to perform a product receipt for example. Correcting data transmission/receiving failures can often take days to resolve causing “un-received” product to build up in receiving locations and further slowing supply chain velocity.

While the Internet of Things technology is still in its infancy, the technology is progressing rapidly. Sensors are getting smaller, battery life is getting longer, and prices are coming down. In addition to location information these sensors are capable of providing a large volume of data about physical product conditions like temperature, exposure to light, exposure to shock and vibration etc. “You want to know something about a product – there is a sensor for that!” While not dependent on 5G networks today, the rollout of 5G means near real-time data can be retrieved about a product and its location and storage conditions almost anywhere any time. This data is not dependent on the successful execution of file transfers or transactions – data about the product is simply a product attribute that changes dynamically as product moves or conditions change.

The other major challenge of managing the extended supply chain is all of the data is not entirely within one system or even within a single organization. ERP has evolved from simple material requirements planning to resource requirements planning to finance to enterprise resource planning as we know it today and while much of a company’s business information can be extracted from their ERP system, ERP barely extends beyond the company’s 4 walls. On top of that, most companies use separate systems for specific purposes. While they may exchange data with the company’s ERP system, they do not truly integrate with it.

As an example, let us say a wholesaler is requesting credit for a returned product from a manufacturer. To determine the amount of credit to be issued, the manufacturer might want to know when the product was shipped to the wholesaler and what price the manufacturer charged the wholesaler – probably easy enough. But now let us, further, say that the wholesaler had previously sold that product to a hospital at a contract price set by the manufacturer and then charged the manufacturer back for the difference between the price the wholesaler paid the

manufacturer when they initially purchased the product and the contract price the wholesaler charged to their customer. In this case the manufacturer would want to credit the wholesaler the amount the wholesaler paid for the product less any amounts that the wholesaler charged the manufacturer for the difference in purchase price vs contract price. Because the data around the sales price to the wholesaler is in one system and the chargebacks paid to the wholesaler are in a separate system this data can be very difficult to retrieve.

CalQLogic's TriggerWare provides data virtualization infrastructure and mechanisms to correlate information from a huge number of disparate, distributed data sources. Data sources include standard databases, APIs and web services, documents, standard databases, ERP, CRM, and sensor streams. Unique in the marketplace, developers have the convenience of querying ALL data sources using a logical query language like SQL. In addition, TriggerWare also provides complex event correlation for data that inherently has a time component, such as sensor data or log data.

Correlating event data over time allows TriggerWare to perform predictive analytics through machine learning. As an example, let us say that you regularly import a product from a contract manufacturer in Europe. You have a standard planning value of 30 days from the time production starts until the product is received. Over time, you would have built up a history of these shipments. The predictive analytics component of TriggerWare can analyze those previous product deliveries and by comparing historical event data to the current set of events predict when your current product order will arrive.

Value Beyond Compliance

We have demonstrated above how the SDxS framework can be used to meet the product tracing requirements set forth in the DSCSA. We have also discussed that by monitoring receiving and shipping events across disparate data sources up and down the supply chain exception alerts could be generated to highlight receiving or shipping that do not have a corresponding shipping or receiving event could be used to detect products potentially entering the supply chain illegitimately.

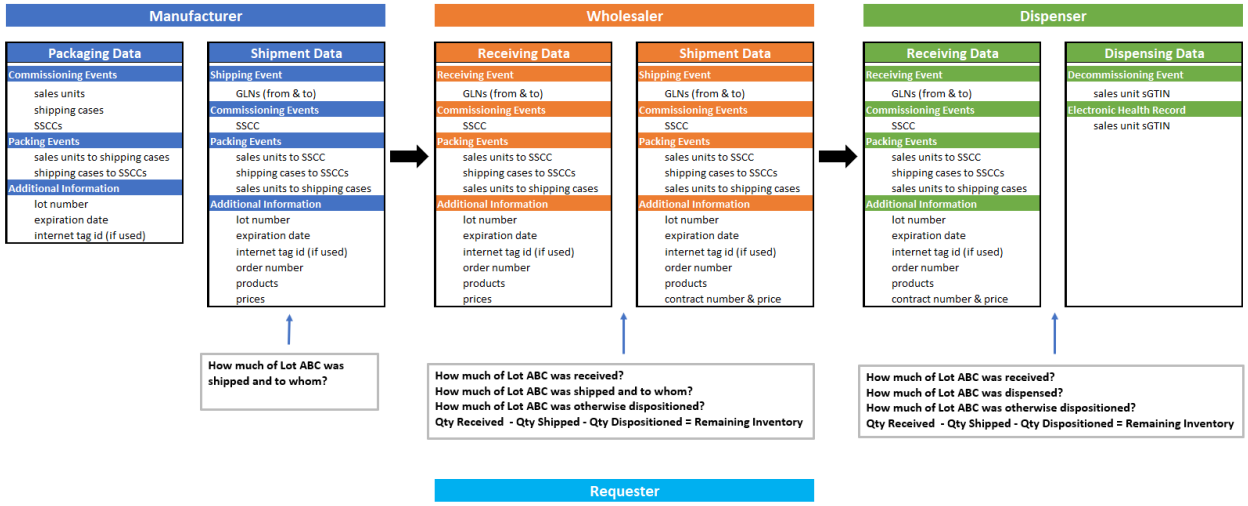
We have also discussed how the lack of a well-defined canonical output across systems providers results in the need for longer than necessary times to make connections between trading partners, difficulty in exchanging serialization data and reduced supply chain flexibility. And that how the use of a common company location identifier (ala GLNs and sGLNs) can ensure that all supply chain participants can share a common view of each trading partner on the network.

It is just as true today as it was in 1959 when noted IBM programmer and instructor George Fuechsel coined the phrase "Garbage In / Garbage Out".

So, with all caveats out of the way let's look at other ways robust supply chain data could be used to provide value by decreasing costs or increasing benefit across the supply chain.

- **Recalls**

Certainly, one of the most obvious uses of extended supply chain data would be in the support of product recalls.



Understanding the answers to the following question helps to provide an answer to how much recalled product was shipped, to whom the product was shipped, and how much recalled product is in inventory and where that product is located.

- How much product was shipped by the manufacturer and to whom?

- How much inventory was received by wholesale distributors? (from manufacturer or as returns)

- How much product was shipped by wholesale distributors and to whom?

- How much product did wholesaler distributors disposition / destroy?

- How much product did dispensers receive?

- How much product did dispensers return or disposition?

- How much product did dispensers dispense?

Product with IOT location sensors could easily be located in facilities like hospitals that have multiple locations where product could be stored either by geofencing those locations or using portable readers within the proximity of the product.

o Drug Shortages

Like recalls, dealing effectively with drug shortages is about knowing where product is located. Understanding how much product was received by any location less how much product was shipped or dispensed by that location can provide valuable insight as to how much product is in inventory across the supply chain and where that product is located.

What is unique about drug shortages versus recalls is that recalls tend to be very specific to a particular product or lot(s) of product whereas drug shortages can apply to multiple products of a certain class or group that can easily be substituted.

If a particular product is in short supply, it would be helpful to know if there is another product / brand that could be substituted. For example rather that querying inventory for each manufacturer that produces sodium bicarbonate injection using an advance analytics tool like CalQLogic's TriggerWare could be used to attached to a database that lists all the manufacturers of sodium bicarbonate injection and their particular products - and then query supply chain data for all the inventory (and locations) of sodium bicarbonate injection supply chain wide.

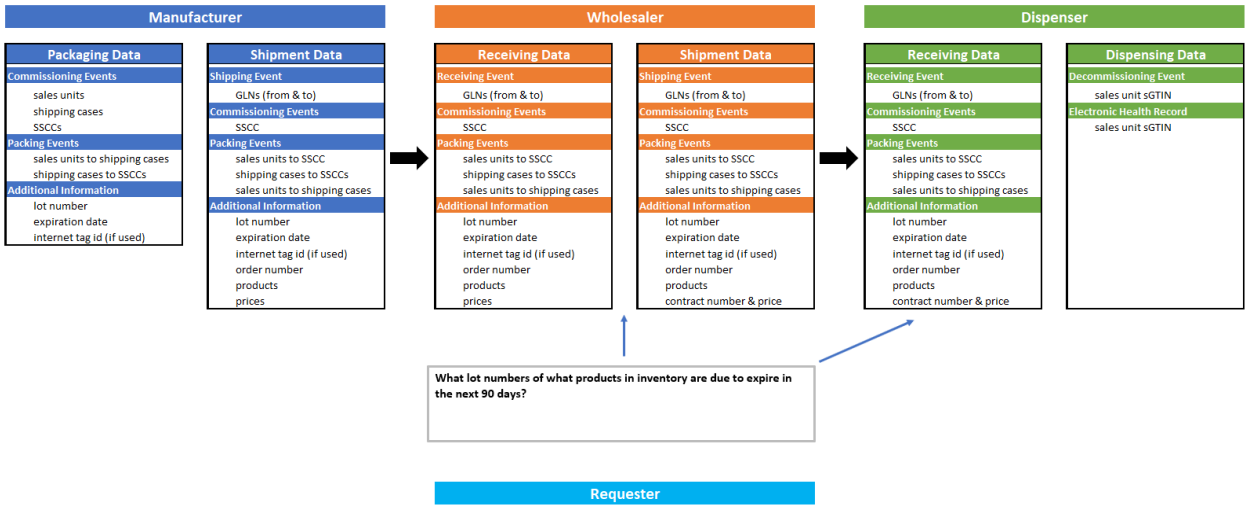
Access to supply chain data would also be helpful to identify "manufactured" where a particular supply chain participant secures excess inventory of products in short supply to resell those products at much higher prices once the drug becomes unobtainable.

- **Effective Supply Chain Decisions**

Everyday planners in pharmaceutical companies are making decisions about when to produce a product and how much to produce. These decisions are made based upon inventory of product on-hand and a projection of sales called a sales forecast. Sales forecasting comes with a great deal of uncertainty – if sales exceed forecast you run the risk of short supply, if sales underperform the forecast inventory increases. It's a difficult juggling act of managing manufacturing resources and working capital. Uncertainty in the sales forecasts is compensated for by investing more capital in inventory – just carry enough inventory so that you never run out. At the same time, you run the risk of committing manufacturing resources to making products you don't need sometimes at the expense of other products. Using extended supply chain data could give planners better insight to inventory positions for a product across the supply chain and provide useful insights into real demand. We estimate that billions of dollars of manufacturer inventory could be converted to cash – reducing the costs of manufacturing while improving drug supply availability – simply by providing better insights to what is happening in the extended supply chain.

- **Expired Product**

Every year significant amounts of product go short-dated and are destroyed. Sometimes that short dated product finds its way into relief organizations where it can be used, sometimes it sits on a shelf waiting to be expired so that it can be returned for manufacturer credit, and sometimes no one knows the product has expired until they go to use it. Whatever the reason, it's a cost that can and should be avoided whenever possible. We have already shown that visibility of supply chain data can provide insights as to what lots of product are located where. As expiration dates are tied to product lot numbers it's a relatively simple analytical exercise to determine where products set to expire are located. Adding IoT sensors to products make locating products with multiple stocking locations like hospitals even easier to locate.



- **Adverse Events / Pharmacovigilance**

Pharmacovigilance and Adverse Event Reporting and Investigation consume significant regulatory and pharmaceutical company resources. Today we have little insight as to what impact different supply chain paths have on drug products. While some may be obvious like leaving a container of product on the tarmac in July in Miami, but other operations may have a negative impact on a drug product that is less obvious. Certainly, using IoT sensors to measure and record the conditions around how a product is stored and handled over time can provide valuable insights. However, correlating adverse events with tracing data through the supply chain could provide insights as well. Looking at the supply chain paths of different drugs for which adverse events are reported may point to a common node in the supply chain that has a statistically higher correlation with adverse events.

- **Last Mile Inventory Management**

Sometimes at the end of the supply chain, a customer receives its shipments, and stocks its shelves or its warehouse locations and all is well. But in other situations that product enters another supply chain that can be so dynamic, fluid and complex, that it is not practical to expect people to transact manually with a system to keep information about product movement updated. This is where technologies like IoT really shine. Forget about having a smart refrigerator reminding you to buy milk! Think about the millions of dollars of pharmaceutical products in every storage location, crash cart, ambulance etc. of a major healthcare system.

IoT sensors combined with geofencing capabilities have the potential to record every product movement into or out of a storage location anywhere. Precise management of inventory has the potential to reduce investment in working capital, reduce waste and obsolescence, and ultimately improve the quality of healthcare.

- **Contracts / Chargebacks / Reverse Chargebacks**

Chargebacks are a discounting mechanism used by manufacturers and wholesalers that allows a manufacturer to provide preferential pricing to customers who are serviced by wholesalers.

Manufacturer's will typically negotiate a contract with group purchasing organization (GPO) to provide preferential pricing for all members (e.g. hospitals) of the group.

Because manufacturers do not sell to group members directly and sales are managed by wholesalers, manufacturers must rely on wholesalers to manage the terms of the contract.

This requires the wholesalers to duplicate the contract including keeping prices and member lists up to date.

When a wholesaler sells a product to a member the wholesaler sells the product at the contract price – which is a price that is lower than the price the wholesaler paid to acquire the product from the manufacturer.

To make up the difference between the price the wholesaler paid for the product and the price at which they sold the product, the wholesaler "charges back" the manufacturer for the difference.

When product is returned to the wholesaler, the wholesaler will typically issue credit for the returned product, and then in-turn request a credit from the manufacturer.

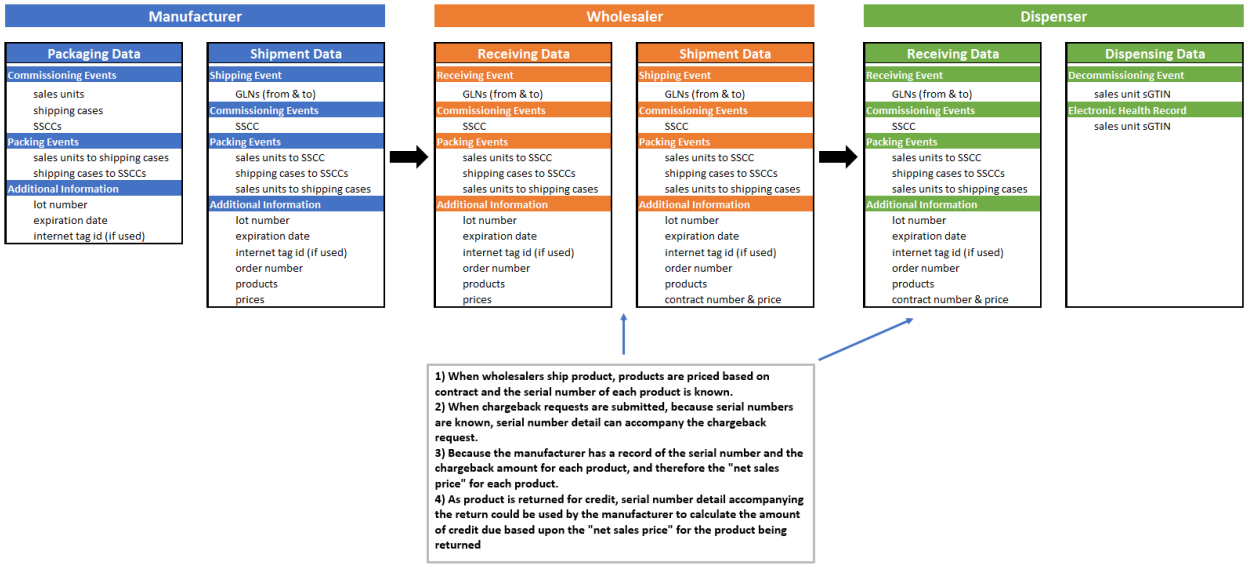
Manufacturers have had an ongoing concern that when wholesalers request credit for product returns, they will request a credit in the amount the wholesaler paid to acquire the product versus the price the wholesaler paid to acquire the product less any amounts charged back to the manufacturer.

Chargeback requests that are submitted by wholesalers to manufacturers are based on the quantity of product sold under a certain contract. Because wholesalers will need to provide serial number detail for each product sold on an order, it goes to say that each package of product sold could be associated with the contract under which it is sold.

Serial number detail contained on orders combined with contract in formation also associated with the order could be used to submit a chargeback request form the wholesaler to the manufacturer that contains serial number detail.

Manufacturers then would be able to calculate a "net price paid" by the wholesaler for a given package of product (price at which the wholesaler acquired the product less chargeback amount = "net price paid").

Then manufacturers could base any future credit (e.g. for returns) based upon the "net price paid").



- **Rebates**

If the above contract / chargeback / reverse chargeback model leaves your head spinning, you are not alone. It has been around for at least 30 years and was complicated to administer then.

If the objective is to provide a discount mechanism to provide preferential pricing to certain customers, or groups of customers, while still having physical shipments processes by wholesalers a simple answer might be a rebate mechanism.

In this model, manufacturers would still negotiate a contract with group purchasing organization (GPO) to provide preferential pricing for all members (e.g. hospitals) of the group.

However rather than have contracts duplicated and administered by wholesalers, wholesalers would price their products in a competitive market.

Group members (e.g. hospitals) would still purchase products from wholesalers.

Because dispensers would be required to perform receipts of serialized product and potentially create dispensing events as well, these events could be transmitted to the manufacturer of the product who then would issue a rebate for each dispensed item.

This model eliminates millions of dollars in duplicate contract administration at both the manufacturer and the wholesaler.

It could eliminate the chargeback process completely and revenue leakage associated with duplicate chargeback submissions and reverse chargebacks.

And provide manufacturers with a rich stream of data that is of higher quality than what they are able to purchase today.

Predictions / Conclusions

It's been 2298 days since the DSCSA was enacted with 1354 days until we need to exchange transaction information including product identifiers and transaction statements in a secure, interoperable, electronic manner.

So, let's look at where we are today.

- ➔ As of November 27, 2017, Transaction History, Transaction Information and Transaction Statements (collectively T3) were to be exchanged electronically between trading partners.
- ➔ The February 2020 report from the Office of the Inspector General OEI-05-17-00460 found that "Drug product tracing information can be used to trace the ownership, but not the physical movement, of selected drug products through the supply chain. Not being able to trace a drug's physical movement delays FDA and other investigators and makes it more difficult to ensure that potentially harmful drugs do not enter the supply chain.".

  The OIG went on to say:

  "We found that the ownership of 37 of 44 selected drug products could be traced through the supply chain using drug product tracing information that the Drug Supply Chain Security Act (DSCSA) requires. Seven selected drug products could not be completely traced to manufacturers. Typically, this was because tracing documents exchanged between the wholesale distributor and manufacturer were missing or had mismatched tracing information. In one instance, a wholesale distributor refused to provide tracing documents. When tracing information is missing or mismatched, a complete tracing record for a drug product may not always be available to support investigations of suspect or illegitimate drug products in the supply chain, which could delay investigators. Indeed, staff at the Food and Drug Administration (FDA) reported that accurate tracing information is critical to identifying a drug product quickly in the event of a recall or when removing an illegitimate drug product from the supply chain.

  Additionally, for 21 of 44 selected drug products, we found that—unlike with their ownership—we could not trace their physical movement through the supply chain using tracing information. We could not identify the shipping locations of trading partners (e.g., manufacturers, wholesale distributors, and dispensers) or third-party logistics providers that shipped or stored the drugs on behalf of the trading partners. Although the DSCSA does not require this information, should FDA not have access to this information in case of a drug safety emergency, FDA and other investigators would need to request additional documents, which could delay investigations and hamper FDA's ability to identify sources of potentially harmful drugs in a timely manner."

Not a glowing report and the sample taken by the OIG is probably representative of the supply chain in general. While a lot of effort could be expended getting all supply chain participants to be compliant in successfully exchanging the T3 data, the systems used to transmit that data would be rendered obsolete in 2023 by systems used to exchange transaction information that includes product identifiers.

November 27, 2017 was also the date by which manufacturers were to encode product identifiers in a 2-dimensional data matrix barcode when affixed to, or imprinted upon, a package

and included in a linear or 2-dimensional data matrix barcode when affixed to, or imprinted upon, a homogeneous case.

With the help of 12 months of deferred enforcement by the FDA, and some liberal provisions for grandfathering products not bearing product identifiers, manufacturers are today largely compliant. There are still instances where labeling is not compliant with GS1 standards, but these issues are being identified by downstream trading partners and corrected.

The ability to verify the product identifier was also a requirement placed on manufacturers beginning in November of 2017 and on wholesalers in 2019 for those products the wholesaler intended to resell.

The requirement to verify the product identifier on a saleable return was a wake-up call for industry. It soon became obvious that while manufacturers who placed product identifiers on their packages were quite capable of verifying those product identifiers on a small scale, a systematic approach was needed to perform verifications at the speed and magnitude needed to support the saleable returns process of larger wholesalers.

The initial approach to meeting the demand for the verification of saleable returns was for manufacturers to send the serialized data with each outbound shipment. This soon highlighted several issues:

1. In order to send data to downstream trading partners required that the standardized numerical identifiers of the sales units within a shipping case needed to be aggregated to the standardized numerical identifier of the shipping case. As aggregation was not a requirement of the DSCSA, some manufacturers and CMOs elected not to make the additional investments in the equipment required to aggregate sales units to shipping cases.

   Given that there is a little over 3 years before product identifiers are required to be exchanged electronically between trading partners, it is unlikely that manufacturers who are not aggregating today will be in a position to provide aggregated data to downstream trading partners in 2023 without a clear mandate to do so.

2. As the DSCSA only requires wholesalers to verify the product identifiers of products that they intend to resell, or as part of a suspect product investigation, some wholesalers have elected not to resell returned products thereby eliminating the need for any investment in systems to exchange serialized data.

3. Similarly, the DSCSA verification requirements placed on dispensers is such that very few of them have made any investment in systems to exchange serialized data.

   Like manufacturers who are waiting for clear mandates to aggregate data, we do not expect investments on the part of smaller wholesalers or dispensers to make investments in systems to exchange serialized data until they are required to do so. At that point the learning curve will be too steep to successfully exchange data with trading partners by 2023.

To the industry's credit, they recognized that the exchange of serialized data would not be in place to meet the verification requirements the DSCSA places on various supply chain participants.

As such, they developed new technologies in the form of a Verification Router Service (VRS) which is capable of near real time verification of product identifiers at scale.

One of the hurdles we see to the successful exchange of serialized data between trading partners is that each trading partner must format the data they wish to send in a way that can be received by the receiving system. Depending on the downstream trading partner and the system they are using, the upstream trading partner must be prepared to send data in multiple formats. This approach requires additional time and testing and ultimately reduces supply chain flexibility. We should strive to avoid situations where it takes more time to set up a trading partner connection that it takes to ship product. A better approach might be for solution providers to output to a strict canonical file format that could be processed by any other solution.

At the same time, new technologies like IoT are evolving quickly in terms of capability and price that offer the promise of tracking products through the supply chain without requiring complex integrations between disparate systems.

While the industry has made significant progress over the past 6 plus years, that progress has not occurred in equal measure across the supply chain. Unless the FDA can begin to articulate guidance on the interim steps the industry needs to take on the path to interoperability, we see the chances of hitting a 2023 deadline as improbable.

Implementation of the DSCSA is a complex supply chain project on a massive scale. We are trying to digitally replicate the movement of product as it moves through the supply chain. To do this effectively we need to capture information about a product every time something happens to that product – when it is shipped, when it is received, when it is destroyed or when it is dispensed – otherwise the data we have collected does not match the physical reality.

The industry has done a remarkable job at developing the business processes, adopting/adapting the GS1 standards to support those business processes and demonstrating how EPCIS transactions can be used to capture physical product movement in the supply chain. It really is time for the FDA to get more prescriptive in moving all the industry players in a common direction.