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THE PEW CHARITABLE TRUSTS

Implementing a Pharmaceutical Serialization and Traceability System in the United States:

Stakeholder Perspectives and Investments

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Executive Summary

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The U.S. pharmaceutical supply is considered one of the world's safest, and the distribution system is well regulated. Deficiencies and gaps persist, however, allowing unsafe medicines to be knowingly introduced into legitimate channels of commerce. Compromised pharmaceutical products recently identified in the U.S. drug supply chain include drugs that have been stolen, diverted, or purchased illegally, as well as outright counterfeit, substandard, and contaminated versions of critical medicines.[1]

Breaches in the drug distribution system pose health risks to patients and financial risks to supply chain stakeholders and taxpayers. In 2012, for example, the U.S. Attorney for Southern New York uncovered a significant drug diversion and resale scheme that cost the New York Medicaid program more than $500 million and put untold numbers of patients at risk from compromised medicines.[2]

Crackdown on Medicaid Fraud and Diverted Prescription Drugs

"The scheme to collect, aggregate, and resell costly prescription drugs was bad medicine in three ways: profiting so obscenely by breaking the law is the very definition of unjust enrichment. The scheme was theft, plain and simple, from a program funded by taxpayers. And the scheme posed serious health risks at both the collection and distribution ends. People with real ailments were induced to sell their medications on the cheap rather than take them as prescribed, while end-users of the diverted drugs were getting second-hand medicine that may have been mishandled, adulterated, improperly stored, repackaged, and expired." [3]

– *FBI Assistant Director in Charge Janice K. Fedarcyk, as quoted in a press release from the U.S. Attorney's Office that announced Medicaid fraud charges involving the diversion and trafficking of prescription drugs (July 2012)*

In 2012, the U.S. Food and Drug Administration (FDA) issued a warning to health care providers and patients that a counterfeit version of Avastin®, a cancer drug, was missing its active ingredient and might have been purchased by a number of medical practices in California, Texas, and Illinois.[4] Regulators later determined that the fake drug was introduced into the United States through a series of wholesalers. More counterfeit cancer drugs have since been discovered in the United States.[5]

Landmark federal legislation was passed to help address these risks in November of 2013. The Drug Quality and Security Act establishes a national electronic system to trace and verify unique, serialized packages of medicine as they move from the pharmaceutical manufacturer through wholesalers to the pharmacy. Both state and federal regulators have sought to advance such measures for many years and, prior to the passage of the federal law, companies were preparing to comply with a similar electronic drug tracking requirement set by the state of California.

Regulators are now preparing to work with affected drug supply chain stakeholders to implement the federal law and develop technical guidelines for its operation. However there remains a lack of credible public information on stakeholder preferences across sectors on the optimal features of a serialization and traceability system and the anticipated investments needed to implement such a system.

To address this information gap, Booz Allen Hamilton and The Pew Charitable Trusts jointly conducted a qualitative assessment of stakeholder perspectives across the U.S. pharmaceutical distribution supply chain, including the manufacturing, wholesale, and dispensing sectors. An online questionnaire and in-depth interviews were conducted prior to the passage of the Drug Quality and Security Act, to gather information from members of the supply chain, as well as from the vendor technology industry that supports them. The responses are aggregated, and the companies are not identified.

This analysis offers a unique, high-level snapshot of industry investments, expectations, and system preferences to inform implementation of the Drug Quality and Security Act. It will help regulators understand industry perspectives, and shed

light on the steps the FDA and supply chain businesses from manufacturers to pharmacies must take as they put new protections in place to maintain safety and security in the nation's drug supply.

Key Findings and Respondent Preferences

Participants in the study affirmed that protecting patients from compromised and unsafe medicines was the ultimate goal of improvements to drug distribution security systems. Although existing state laws were driving implementation efforts at the time these perspectives were solicited, stakeholders strongly preferred a single nationwide system as opposed to a patchwork of multiple state requirements. The majority of respondents also preferred a system that required participation across all supply chain sectors.

Two major obstacles to implementation cited by respondents were the lack of clear regulatory expectations and uniform system design. While the new federal legislation will help address these concerns, a number of regulatory standards must still be developed. Respondents made specific appeals for clarity on how data should be shared between trading partners, and noted they would need adequate advance time to develop and test their systems in order to minimize supply interruptions.

Cost was perceived as a challenge for many respondents; however, the study found that estimates for implementing a system ranged widely across supply chain sectors. Manufacturers estimated costs in the tens of millions of dollars overall, but expressed notable variation in estimates for costs at the line, site, and enterprise level due to diverse business needs and technology choices. Manufacturers also reported that they were already making large investments in technology. All responding manufacturers said that serialization of drugs—a necessary precursor to traceability and required by the new law—was a current or planned feature of their system.

Information on anticipated costs for wholesalers and dispensers was more difficult to obtain. Vendor estimates suggest that large national wholesalers might experience costs consistent with large manufacturer estimates, while large chain pharmacy costs could be slightly less. Estimates from cloud-based service technology providers, while theoretical, suggest the potential for a very low-cost solution for independent pharmacies. One estimate predicts a cost of $2,000 for initial implementation, and an additional $2,000 in annual recurring service fees.

1. Overview and Background

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1.1 Scope

The study focused on the distribution system for drugs in the United States. Within this system, pharmaceutical manufacturers, wholesalers, and dispensers work together to deliver high-quality pharmaceutical products and ensure patients have the medicines they need.

Drug distribution begins with the manufacturer of a finished product. Once a medicine is packaged and leaves the production phase it enters domestic distribution. It passes from a manufacturer to a wholesaler or a series of wholesalers, then potentially through a repackager. Finally the drug is delivered to a pharmacy or hospital, where it is dispensed to the patient. Products also may be returned and resold. A finished product's distribution path is often simple; yet it can also be complex, passing through multiple intermediaries before the drug reaches consumers.

1.2 Risks to the U.S. Pharmaceutical Supply

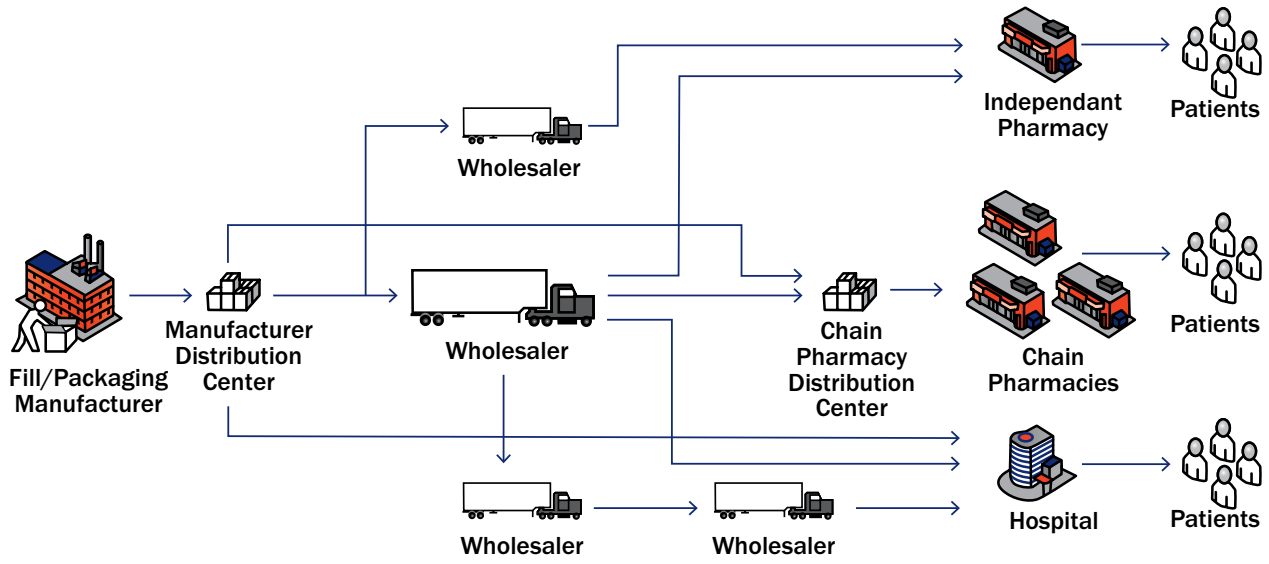
The supply chain is threatened by a number of persistent and ongoing incursions, each with potentially serious public health consequences. These illegal activities include: creating counterfeit pharmaceutical product with inactive or harmful ingredients, outright theft and diversion of legitimate pharmaceuticals, and illicit schemes such as replacing a drug with a lower-dose product. A comprehensive supply chain security solution, which is the goal of the new federal legislation, will do much to mitigate these risks.

1.3 Pharmaceutical Serialization and Traceability Systems

1.3.1 What Are Serialization and Traceability Systems?

A number of countries, as well as some states in the U.S., have proposed or established solutions to improve control of the supply chain and enhance visibility of pharmaceutical product during distribution. These include: employing drug pedigrees (a transaction history for a given shipment of medicines) which may be captured electronically or on paper, placing unique identifying serial numbers on drug packages, and establishing data sharing and data management protocols to allow on-demand checking of a drug's serial number and/or transaction information. This last element may include identifying a product's destination in the supply chain (drug tracking) as well as where a product has been (drug tracing).

Exhibit 1 | Illustration of the U.S. Supply Chain for Pharmaceutical Distribution



Diverted and Stolen Medicines

Medicines that are diverted* or stolen and then illegally reintroduced into the legitimate supply chain present significant risks to the public's health. These drugs may have been improperly handled, stored under unknown conditions or temperatures, exposed to contaminants, or even deliberately adulterated.[6] In 2012 the U.S. Attorney for Southern New York uncovered a massive criminal diversion and relabeling scheme where drugs were illicitly purchased from patients, resold back into legitimate distribution channels, and ultimately delivered to pharmacies. The scheme cost the state Medicaid program more than $500 million and put untold numbers of patients at risk from medicines that may have been compromised. According to the Manhattan U.S. Attorney, "defendants ran a black market in prescription pills involving a double-dip fraud of gigantic proportions. It worked a fraud on Medicaid—in some cases, two times over—a fraud on pharmaceutical companies, a fraud on legitimate pharmacies, a fraud on patients who unwittingly bought second-hand drugs, and, ultimately, a fraud on the entire health care system".[7] In 2009 thieves stole more than 129,000 vials of insulin, a key treatment for diabetes. The temperature-sensitive medicine was later sold back into distribution through a series of licensed wholesalers in more than two states, ultimately reaching retail chain pharmacies in Texas, Georgia, and Kentucky.[8] Some patients who received the product reported health complications.[9]

Counterfeit Drugs

Counterfeit medicines are pharmaceutical products that imitate the appearance or packaging of drugs from a licensed manufacturer, and that may be introduced into the legitimate pharmaceutical supply chain via regular distribution channels. Counterfeit medicines pose a potentially significant risk to the public health because they often appear physically indistinguishable from the genuine product. These drugs may contain only inactive ingredients, incorrect ingredients, improper dosages, or even dangerous sub-potent or super-potent ingredients. In February 2012 the Food and Drug Administration (FDA) issued a warning to healthcare providers and patients that a counterfeit version of Avastin®, a cancer drug, may have been purchased by a number of medical practices in California, Texas, and Illinois.[10] Regulators later determined that the fake drug was introduced into the U.S. through a series of wholesalers. More counterfeit cancer drugs have since been discovered in the United States.[11,12]

Congress–supported by numerous diverse public health and industry stakeholders—passed the Drug Quality and Security Act in 2013 to strengthen the drug supply by creating a national system for serializing packages of medicine, with the eventual ability to trace and verify these packages as they move through distribution channels. This national system is intended to protect patients and consumers from compromised medicines by identifying stolen, diverted, or counterfeit drugs before they enter legitimate distribution channels.

The new law requires the placement of a unique serial number on each package of drug four years after the law's enactment, and requires the establishment of technologies to permit verification of these serial numbers to ensure the drug's legitimacy. The law establishes an electronic traceability system at the unit level (the smallest individual package of a drug that is sold by a manufacturer), which will be operational ten years following enactment. Beginning one year after passage supply chain stakeholders will participate in an interim system that traces drugs by their lot number. Stakeholders will work with the FDA to establish specific data exchange and storage parameters for the eventual unit-level standard.

* Drug diversion is the removal of drugs from legitimate distribution channels through methods including the illicit purchase of drugs from patients and trading in drugs not approved for sale in the U.S.

1.3.2 Legislative and Regulatory Background

Drug pedigree laws have been in existence in the United States since the Prescription Drug Marketing Act (PDMA) was signed into law in 1988. In December 2006 FDA regulations to implement the pedigree provisions of the law were challenged in court by independent wholesalers. The courts granted a stay of the FDA's rule, citing inconsistencies between the rule and the original law.[13] In the Food and Drug Administration Amendments Act (FDAAA) of 2007 the FDA was instructed to issue new standards on drug tracking and authentication.[14] Those standards still had not been proposed, however, by the time the Drug Quality and Security Act was passed in 2013.

State governments did not stand still in the absence of an enforceable national requirement. According to the Healthcare Distribution Management Association (HDMA), 29 states have enacted some kind of drug pedigree law.[15] Drug wholesalers operating in multiple states are required to understand and obey the specifics of each law in each state. Most of the 29 state laws conform to the concept of "normal distribution," which is typically defined as a path from the manufacturer to a single wholesaler, who then ships to a pharmacy. Under these laws, pedigrees are only required when a drug departs from the "normal distribution" path.

In 2006, Florida enacted a drug pedigree law which states that wholesalers who purchase a given drug from anyone other than the manufacturer must provide their customers with a pedigree that documents the supply chain history of that drug back to the manufacturer. The pedigree may be in paper or electronic form, and must include signatures from each person receiving and shipping the drug at each stop in the supply chain.[16]

The most comprehensive drug pedigree law was enacted by California in 2004. After multiple implementation delays, the law was scheduled to take effect in phases starting in 2015; however this law is now preempted by the new federal statute, as are all other state drug pedigree laws. California's law was the only state law that affected drug manufacturers, requiring the smallest saleable package of drugs to bear a unique identification number. These serial numbers had to be documented on the drug pedigree, which was required to be electronic. This pedigree started with the manufacturer and extended to the pharmacy. Each supply chain trading partner was required to update the pedigree upon receipt and upon shipment, as well as to certify that the information contained therein was true and accurate.[17]

A growing number of countries outside the U.S. have enacted some form of drug traceability, many with the goals of reducing national health care spending and preventing insurance reimbursement fraud. Italy was one of the first countries to pass such a law. Italy enacted the "Bollini" law in 2000, requiring drug serialization and tracking to the point of sale.[18] Turkey has a similar system that has been in place since 2012. Manufacturers or importers are required to apply unique serial numbers to all drug packages entering the country, and valid serial numbers are a condition of reimbursement by the national government insurance program.[19] Other countries, such as China and Brazil, are also in the process of implementing drug serialization requirements.[20] In 2011, the European Union established a directive that would require all member states to enact their own drug serialization and "track and trace" regulation by 2014.[21]

Global and U.S. requirements for serialization and traceability systems have resulted in system investments by supply chain sectors. Manufacturers that need to comply with existing standards in multiple countries, for example, are likely to have begun adding serialization capabilities to their packaging lines. Prior to passage of federal traceability legislation in 2013, California's law also drove early investments in

serialization. The California law required prescription drugs sold in the state to bear unique serial numbers by 2015.† Neither manufacturers nor many wholesalers know where any given unit of drug will end up in the United States. As a result, many companies found it necessary to plan for adding unit-level serial numbers to all medicines sold into the U.S. market to ensure regulatory compliance for California.

U.S. national wholesalers, repackagers, and some regional wholesalers have had electronic pedigree software in place since 2006 to meet the Florida and U.S. federal PDMA pedigree regulations. However, this software may not be suitable for sharing and exchanging information on serialized drug products.

† Specifically, the California law required that companies serialize one half of the drugs sold in California by 2015, and all drugs sold in California by 2016.

2. Methodology

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2.1 Overview

The study captures both qualitative and quantitative information from supply chain stakeholders across sectors in order to assess perspectives and estimated investments needed for an anticipated national drug serialization and traceability system.

Qualitative and quantitative elements were gathered using the following approaches:

- Questionnaire issued to supply chain stakeholders
- Follow-up in-depth interviews with supply chain stakeholders
- In-depth interviews with technology vendors

Section 2.2 describes these approaches in greater detail. Quantitative data was subsequently analyzed as discussed in section 2.3.

Participants in the study include experts and thought leaders from each sector of the U.S. pharmaceutical supply chain—manufacturing[†], wholesale distribution, and dispensing—as well as technology vendors and consultants that support supply chain stakeholders in the implementation of serialization and traceability systems.

Data were gathered in a non-attributable fashion: participants were informed that the information collected from them in the questionnaire and via interviews would not be directly attributed to them or their organizations.

Ongoing and iterative engagement with supply chain stakeholders was incorporated throughout the process in order to confirm and validate findings and to ensure that qualitative feedback was appropriately characterized, particularly around cost estimates.

While questionnaire respondents and interview participants were samples of convenience, efforts were made to minimize bias by gathering information from all affected sectors within the supply chain and by working with major supply chain trade associations to ensure wide distribution of the questionnaire.

All information for this study was collected prior to the passage of the federal legislation. While respondents were asked to provide perspectives on a national, unit-level traceability system, which the legislation establishes, it is possible that responses reflect different system assumptions than what are now required by statute.

The study is intended to be useful to regulators and stakeholders as they implement the new national law, and no position on any specific system framework or proposed standard is implied by the findings.

2.2 Data Collection and Analysis

2.2.1 Questionnaire Issued to Supply Chain Stakeholders

The project issued a questionnaire to stakeholders in pharmaceutical manufacturing, wholesale, and dispensing sectors to solicit both qualitative perceptions and opinions on features of a national serialization and traceability system, as well as the estimated costs to implement such a system (see Appendix A for full questionnaire).

The questionnaire was structured around four system components: serialization, local data, aggregation, and shared data. For serialization, the study assumes use of 2D (two dimensional) data matrix barcodes. “Local data” is technology that enables an organization to internally capture and manage serialization data. “Aggregation” technology permits the creation of parent-child relationships as serialized products are packed into larger containers. For example, a serial number on a case is associated with the serial numbers of each individual packaged unit inside, allowing the unit serials to be identified without opening the case. Finally, “shared data” enables communication of this information between supply chain stakeholders (see Appendix D for a full discussion of the technology increments).

The questionnaire went through a detailed internal and external review. It received an early review by an expert in serialization and traceability systems and software, and was later extensively reviewed by a working group of companies currently engaged in system implementation efforts via their respective trade associations. The questionnaire reflects feedback from these reviewers.

The questionnaire was issued to a broad set of stakeholders across the supply chain using a web-based tool. Companies

[†] The study examines distribution of drugs packaged in their final dosage forms; manufacturers and suppliers of raw materials such as active pharmaceutical ingredients and excipients (pharmacologically inactive substances) are not included.

were issued the questionnaire where direct relationships had been previously established; the questionnaire was also issued via industry trade associations, including:

- Pharmaceutical Research and Manufacturers of America (PhRMA)
- Generic Pharmaceutical Association (GPhA)
- Healthcare Distribution Management Association (HDMA)
- Health Industry Distributors Association (HIDA)
- National Coalition of Pharmaceutical Distributors (NCPD)
- National Association of Chain Drug Stores (NACDS)
- Healthcare Compliance Packaging Council (HCPC)—contract packaging companies only

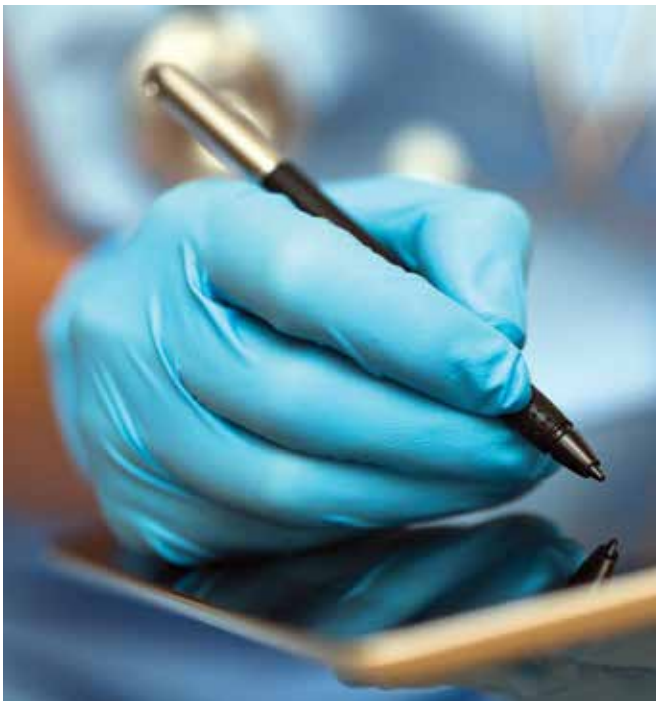
Additional potential respondents were identified through the American Society of Health-System Pharmacists (ASHP). To facilitate completion of the questionnaire, an interactive PDF version was also provided so respondents could easily share the questionnaire within their organization.

The questionnaire web form was open for a three-and-a-half-week period, and responses were returned to the project administrator at Booz Allen Hamilton. Prior to analysis, the names of the respondents and their organizations were removed from the completed submissions.

The questionnaire received a total of 41 responses. The data from 31 of these responses are discussed in this report. A total of ten responses were discarded: eight of the ten were non-responses containing missing values, and the remaining two were duplicates.

Respondents fell into the following sectors, based on their reported primary business:

- Ten pharmaceutical manufacturers, including five branded small molecule manufacturers, one generic small molecule manufacturer, three biopharmaceutical manufacturers, and one contract packager
- Ten pharmaceutical wholesalers
- Eleven pharmacies, including eight hospital pharmacies, one retail chain, one independent pharmacy, and one mail-order pharmacy



2.2.2 Follow-Up In-Depth Interviews with Supply Chain Stakeholders

The project team conducted follow-up interviews with questionnaire respondents to further explore differences in perspectives and cost estimates, and to provide context for discussion of results in the report. Respondents identified their willingness to participate in follow-up interviews in their questionnaire submission.

The project team conducted 11 follow-up interviews with respondents, including six manufacturers, three wholesalers, and two pharmacy dispensers.

In advance of interviews, participants were provided with an interview guide to facilitate the follow-up discussions (see Appendix B). Interview notes were shared with respondents after each interview to confirm their comments were accurately captured.

2.2.3 In-Depth Interviews with Technology Vendors

In addition to collecting estimated investments directly from supply chain stakeholders, the project asked for cost estimates from technology vendors and consultants that support supply chain members in the implementation of serialization and traceability systems.

The project team conducted in-depth interviews with seven established technology vendors, which were identified through conversations with pharmaceutical supply chain stakeholders and existing team knowledge of the industry. The final group of participants represent a range of service categories used to implement serialization and traceability across the drug supply chain: three companies provide software and integration services, one provides data repository and data exchange services, one provides packaging equipment, and two provide consulting services for the overall coordination of the aforementioned categories.

Prior to the interviews, vendors were given a spreadsheet that broke out cost estimate components by industry type and the four system components noted above (see Appendix C). During each interview, cost estimate data was collected to populate the spreadsheet. The completed spreadsheet was then shared with the interviewee to ensure accuracy.

2.3 Cost Analysis

As previously noted, the project collected two sets of cost data: supply chain stakeholders were asked to estimate their own costs to implement a unit-level traceability system, and vendors provided estimated costs for typical or hypothetical clients from each supply chain sector. These hypothetical clients were defined in advance, as follows:

- Medium-sized manufacturer
  - 3 packaging lines per site
  - 4 sites
  - 2 distribution centers
- National distribution wholesaler
  - 17 stations (receiving, picking, returns, and inventory control) per site
  - 28 sites
- Large retail chain pharmacy
  - 4,000 pharmacies
  - 14 distribution centers
- Independent pharmacy
  - 1 pharmacy

For both sets of estimates, the project looked at total costs for system implementation and total annual ongoing costs, as well as costs at different operational levels—including per packaging line, per site, and per enterprise (see Appendix A and Appendix C for additional detail on cost categories).

In order to permit a better comparison between vendor and stakeholder data, estimates provided by manufacturers for their own costs were standardized by multiplying their reported per-line and per-site figures by the number of each for the hypothetical medium manufacturer. Other stakeholder cost estimates could not be similarly adjusted; wholesalers provided data mostly at the enterprise level alone, and the one set of cost estimates received from a pharmacy were not included to protect respondent confidentiality.

Supply chain stakeholders were also asked about labor costs in the questionnaire; however vendors were not asked to estimate the internal labor costs of their supply chain clients.

Some vendors calculated costs in increments other than per-line, per-site, and enterprise level, such as per-transaction fees. In such cases costs were multiplied by the number of transactions the solution provider estimated for the enterprise of each organization type. Total costs calculated using such methods were reviewed by, and verified with, vendors.

2.4 Study Limitations

Because the study relied on a sample of convenience, findings may not fully represent the identified supply chain sectors. Efforts were made to reduce the potential for sample bias by opening participation as broadly as possible for potential respondents. Outreach was conducted directly to individual organizations, as well as through major supply chain industry trade associations (see Section 2.2.1).

The participant group was self-selected and, therefore, may include an over-representation of companies who have been exposed to serialization and traceability technology issues, or that have been engaged in discussions about a national system. As a result, responses on preferences for these systems may not fully capture the perspectives of organizations that have been less exposed or involved; potentially including smaller organizations. Within the dispenser respondent group, health system pharmacies were the majority of respondents.

While concerted efforts were made to collect comparable data points through the use of a common template of typical cost elements, in some cases estimates diverged due to

varying business models or scale of operation. In addition, costs for some system components are not well understood because technologies are not yet in common use or have not been widely adopted in the pharmaceutical supply chain industries.

3. Supply Chain Stakeholder System Preferences and Perspectives

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3.1 Overview

Questionnaire respondents expressed broad support for a national serialization and traceability system, both to avoid the challenge of complying with differing state laws and to improve pharmaceutical supply chain security. Participants wanted all supply chain sectors—manufacturers, wholesalers, and dispensers—to participate in a national system. Regulatory compliance with existing laws was a major driver of implementation efforts, but respondents also saw patient protection as a significant goal of serialization and traceability.

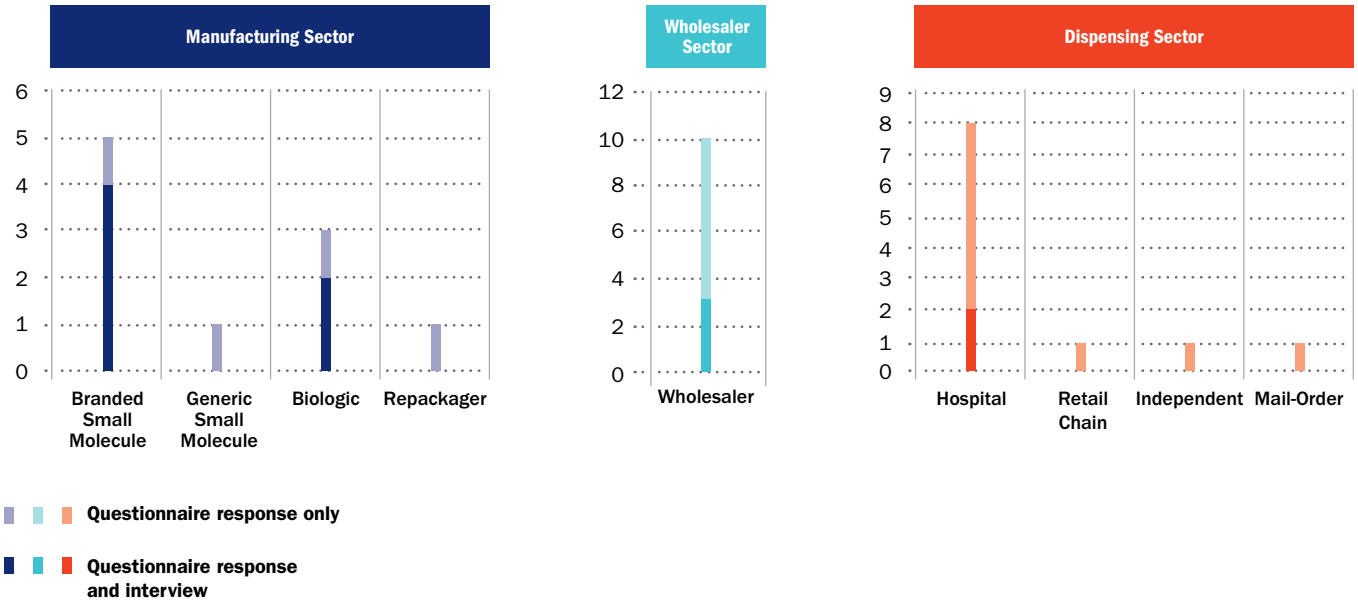
While agreement existed on many points, supply chain members—as a whole and within each sector—prioritized serialization and traceability system implementation differently, and also differed in their understanding of costs and preferences for certain system parameters. Overall, manufacturers viewed implementation as a higher priority than other respondents, and had greater knowledge of and familiarity with the anticipated impacts.

The questionnaire also assessed challenges and benefits associated with serialization and traceability system implementation (see Section 6.) Regulatory ambiguity was cited as a major and ongoing challenge, and uncertainty regarding state expectations and federal requirements meant that some respondents were cautious in making implementation investments. System costs were also reported as a significant challenge. These perspectives may have shifted now that the Drug Quality and Security Act has been enacted.

3.2 Respondent Demographics and Sector Descriptions

A total of 41 questionnaire responses were submitted, with data from 31 discussed in this report. Ten responses were discarded; eight of the ten were non-responses containing missing values, and the remaining two discarded responses were duplicates.

Exhibit 2 | Manufacturing, Wholesaler, and Dispensing Sector Participation in the Study



Responding organizations were grouped into three sectors based on their reported primary and secondary sources of pharmaceutical revenue:

- **Manufacturers:** Companies that produced and packaged finished pharmaceutical products for sale into distribution. This group included branded, generic, small-molecule, and biologic pharmaceutical manufacturers, as well as contract drug repackagers. The companies in this category moved large volumes of drugs—approximately 10,000 to 10 million units per month;
- **Wholesalers:** Companies that purchased and sold medicines during the drug distribution process. All organizations in this group indicated they distributed nationally yet the size of their businesses varied broadly: reported volume ranged from approximately 1,000 to 10 million units per month;
- **Dispensers:** Companies that dispensed medicines to patients. This group included mail-order, independent, chain, and hospital pharmacies. These organizations estimated receiving between 1,000 and 1 million units per month.

Ten manufacturers, ten wholesalers, and eleven dispensers submitted questionnaire responses. Six, three, and two respondents from those sectors, respectively, participated in follow-up interviews.

Questionnaire respondents generally identified their roles as either management or senior management within their organizations. Most respondents who were interviewed indicated that they worked with others in their organizations to compile the information requested by the questionnaire.

3.3 Perspectives on Motivations, Necessity, and Prioritization

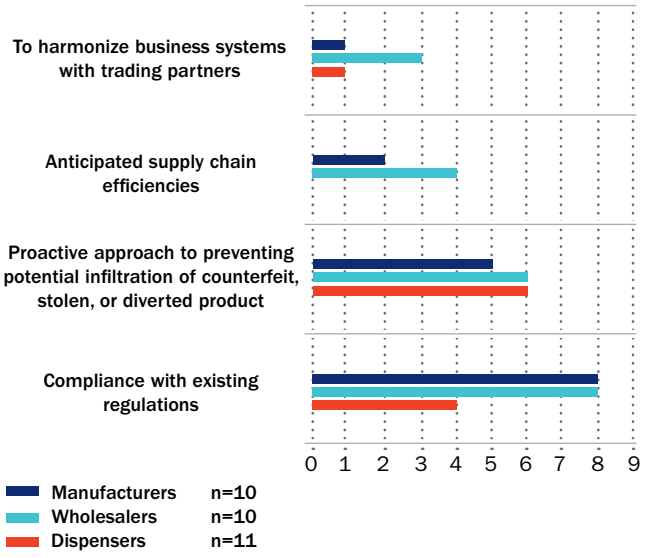
Although this study was conducted prior to the passage of federal legislation establishing a national drug traceability system, stakeholder views on the importance of such a system—and motivations to pursue it—are directly relevant to the law's future implementation.

Among respondents, the top-ranking primary motivators for implementing a national serialization and traceability system were compliance with regulatory requirements and protecting the integrity of the pharmaceutical supply chain from unsafe products (see Exhibit 3). For manufacturers and wholesalers, implementation is mainly motivated by the regulatory environment: eight out of ten respondents in each of these sectors indicated compliance as a primary motivation. Around half of each group—manufacturers, wholesalers, and dispensers—said that preventing counterfeit, diverted, and stolen product from entering the supply chain was a primary motivation. Twenty-six percent of all questionnaire respondents indicated that a national, unit-level system would yield supply chain benefits such as increased efficiencies. Perspectives on system benefits are described in greater detail in Section 6.2.

Overall, establishing serialization and traceability systems was of greater importance to manufacturers than to other sectors. Nine out of ten manufacturers considered implementation to be a high priority, while only two wholesalers and one dispenser expressed similar views.

Through questionnaire responses and interviews participants emphasized that patient protection was the ultimate goal of serialization and traceability systems. More than 80 percent of respondents agreed that such a system would

Exhibit 3 | Selection Frequency of Some Primary Motivators for Implementing a National Serialization and Traceability System



Respondents were allowed to select multiple primary motivations.

positively affect public health by strengthening the distribution supply chain's ability to safeguard medicines and prevent the insertion of stolen, diverted, and counterfeit drugs into the supply chain (see Exhibit 4). These views underscore the importance of robust and timely implementation of the new federal law to ensure it achieves its goal of protecting patients from unsafe products.

Views were mixed concerning another issue: drug shortages. Ten percent thought a serialization and traceability system would help mitigate drug shortages, 53 percent thought there would be no impact, and 20 percent thought drug shortages could be made worse. The questionnaire did not explore whether impact on shortages would be sustained, and it cannot determine whether serialization will help address shortages in the long term. Discussion during interviews suggests, however, that concerns about supply interruptions are related to working through initial system implementation issues with supply chain trading partners, such as successful data exchange and protocols to address errors in aggregation information. Supply issues related to early implementation hurdles would be expected to be temporary.

Federal legislation has now replaced state laws, and perspectives solicited prior to passage reflect strong approval of a single uniform standard. Manufacturers and wholesalers were unanimous in their preference for a national serialization and traceability system over multiple state laws. In addition, 50 percent of manufacturers and 30 percent of wholesalers said that efforts to combat counterfeiting cannot be effective without a national traceability system. Dispensing sector responses differed slightly: 82 percent of respondents said that a national system is needed to combat counterfeiting, and 70 percent preferred a single, national system over state laws.

Exhibit 4 | Respondents' Views on the Effects of a National Unit-Level Serialization and Traceability System

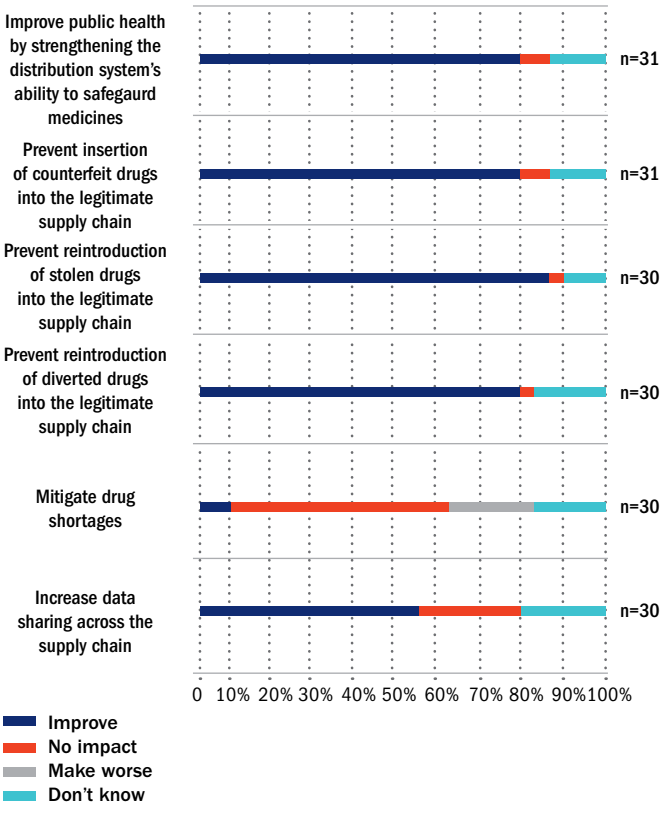
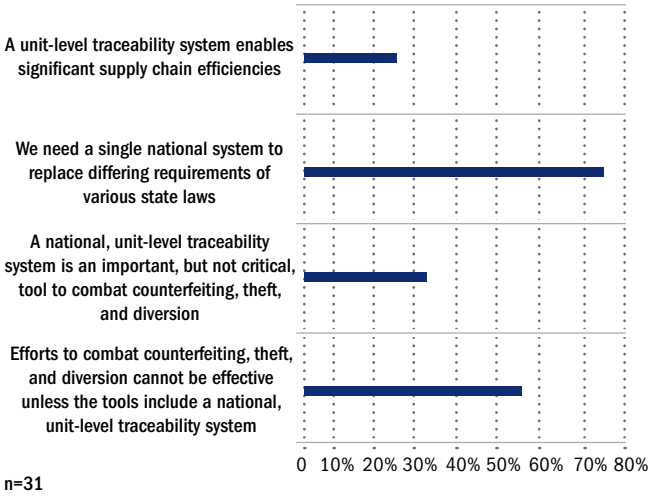


Exhibit 5 | Respondents' Views on Why They Would Prefer a National Serialization and Traceability System



When asked to indicate reasons for not preferring a national serialization and traceability system, no respondent selected "drug counterfeiting, theft, and diversion are not significant problems in the U.S. supply chain" as a response. Nineteen percent of all questionnaire respondents indicated, however, that there are more cost-effective ways to combat these issues than a national serialization and traceability system. Additionally, 23 percent felt that there are too many potential avenues to circumvent the protection that such a system could potentially offer. During follow-up interviews, one respondent noted that improvements to business practices and security have already helped to address these safety concerns.

3.3.1 Desire for Clarity on System Structure and Expectations

A number of participants reported that their implementation plans were affected by a lack of regulatory clarity, both in terms of certainty around system requirements and regulatory time lines. Respondents currently working on installing a traceability system viewed additional clarity as critical to project completion. Other organizations reported that they would wait for greater regulatory clarity before beginning to implement a system. At the time these views were shared, compliance with the California drug pedigree law was a primary focus as a federal law had not yet been enacted.

The passage of the federal serialization and traceability law will help alleviate concerns regarding clarity on system structure and timing; however certain important issues critical to implementation, such as data sharing protocols, are yet to be resolved. During interviews, some participants made a specific appeal for standards on data sharing; they underscored the complexity of collecting, storing, and communicating transaction data, and emphasized the need for clear data exchange standards to build and test this functionality. Federal legislation stipulates that the FDA is to work with the pharmaceutical supply chain industries and other stakeholders to provide specificity on these and other standards.

Lack of awareness was also a concern. Several interviewees, particularly from the dispensing sector and smaller wholesalers, said they were not knowledgeable enough about applicable laws and regulatory requirements. This was true even for organizations that generated significant revenue in California, a state whose drug pedigree law would have required them to participate in an electronic unit-level pedigree system, although these requirements would not have affected wholesalers and pharmacies until mid-2016 and mid-2017 respectively. New federal legislation establishes different requirements on a more extended time line: wholesalers and pharmacies will have to accept only serialized products by late 2019 and late 2020 respectively, and will not have to share traceability information about serialized products until late 2023.

3.4 System Preferences

Successful implementation of the new federal law will rely on ongoing collaboration between stakeholders and the FDA to establish standardized practices and set guidance on system requirements. Supply chain sector participants in this

study expressed a number of preferences on how a national traceability system should be structured. Respondents were divided in some areas, such as how data should be managed and exchanged, but had common preferences on technical standards. Inference—the ability to know what serialized products are inside a closed container without opening it—was seen as extremely important to the success of a traceability system. Regardless of specific preferences, consistency and uniformity was important to most participants. Twenty-two out of 31 respondents preferred the deployment of a single type of system and a single set of standards across all pharmaceutical supply chain sectors.

3.4.1 Supply Chain Partner Participation

Eighty percent of respondents agreed that a national system should apply to all sectors of the supply chain without exception, with similar agreement on the issue within each sector: 90 percent, 80 percent, and 73 percent for manufacturers, wholesalers, and dispensers, respectively.

During interviews some participants expressed frustration with then-current Congressional debate regarding the participation of certain supply chain sectors in a national system—a debate that the participants felt had impeded progress toward federal legislation. Specifically, some respondents remarked that political pressure to exempt pharmacies was problematic, and that all supply chain

Exhibit 6 | Preferences on Where Authentication Should Occur in the Supply Chain if a Feature of a National System

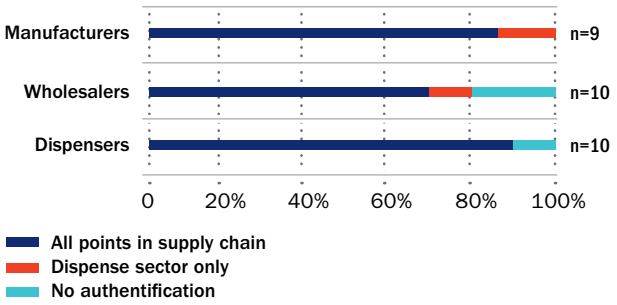
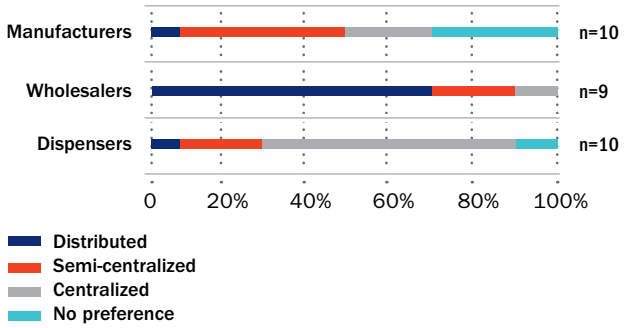


Exhibit 7 | Preferences for Centralized Versus Decentralized Data Model



sectors must participate in a meaningful system with appropriately robust measures to address supply chain and product integrity risks. One respondent noted that pharmacies participate in serialization and traceability systems in other countries, and asked why this should not be the case in the U.S.

3.4.2 Drug Traceability and Authentication Preferences

Half of manufacturer and wholesaler respondents and 64 percent of dispenser respondents agreed that a national system should provide for unit-level traceability.

Agreement among the sectors was less uniform when asked about unit-level authentication, however. Eighty percent of manufacturers preferred this as a system feature, whereas only 30 percent of wholesalers and 36 percent of dispensers preferred it. Yet if unit-level authentication was an assumed feature of a national system all sectors strongly preferred to have this capability at all points in the supply chain, rather than just at the point of dispensing (Exhibit 6).

3.4.3 Traceability Data Storage and Transmission

Respondents were asked which of the following three over-arching models for storing and transmitting data would be preferable for a national serialization and traceability system:

- **Distributed Model:** Each organization stores its own data and is responsible for transmitting it, when required, in a standard format
- **Semi-Centralized Model:** Organizations transmit traceability data to one of a few or several databases that are managed by third parties
- **Centralized Model:** Organizations transmit traceability data to a single repository that could be run by a public or private entity and would likely be managed by the government or an industry consortium

There was no shared model preference among the sectors. Sixty percent of wholesalers preferred the distributed model, 40 percent of manufacturers preferred the semi-centralized data storage and transmission architecture, and 60 percent of dispensing organizations preferred the centralized approach, (Exhibit 7). The new federal legislation does not specify a structure for data management. Stakeholders must work with each other and with the FDA to establish data storage systems that permit compliance with the law.

When manufacturers were asked which data communication standard supply chain stakeholders currently have, or plan to include in a traceability system, 90 percent chose a GS1 EPCIS[§]-based system. Forty percent of manufacturers also indicated that they have included, or planned to include, a GS1 DPMS[**] system. This implies that some manufacturers may include both standards in their traceability systems. Most wholesalers and dispensing sector respondents did not know which standard they would actually use, but when asked for their preference on standards 55 percent of responding wholesalers and dispensers chose EPCIS only, 11 percent chose both standards, and 33 percent had no preference. Additionally, 60 percent of manufacturers and 40 percent of wholesalers have or planned to implement the AS2 standard for secure data transfer. As noted in Section 3.3.1, participants in this survey made specific appeals for clarity on how data would be exchanged between trading partners. The Drug Quality and Security Act instructs the FDA to release draft guidance on interoperable data exchange standards by late 2014.

[**] DPMS stands for Drug Pedigree Messaging Standard, which is a document-based GS1 standard that assists the pharmaceutical supply chain with creating an interoperable system to trace drugs in a way that can comply with existing document-based pedigree laws.

[§] EPCIS stands for Electronic Product Code Information Services, which is a general-purpose GS1 standard designed to enable serial number-related data capture and sharing within and across enterprises in supply chains. GS1 is an international non-profit standards-setting organization.

Carrier Technologies and Serialization Standards

Carrier Technologies

There are three primary options for affixing serialization information to drug packages: one-dimensional (1D) barcodes, two-dimensional (2D) barcodes, and radio frequency identification (RFID) tags. Supply chain stakeholders were asked which technology was preferred by their organization for various types of packages:

- Smallest salable units;
- Cases filled with a single type of unit-level packages;
- Pallets, generally stacked with cases; and
- Totes,[††] which may be filled with one or a mixture of smaller packages.

1D (One-dimensional) Barcode: A barcode that uses a single physical dimension, such as a linear barcode.

2D (Two-dimensional) Barcode: A barcode that uses two physical dimensions, such as a Data Matrix barcode.

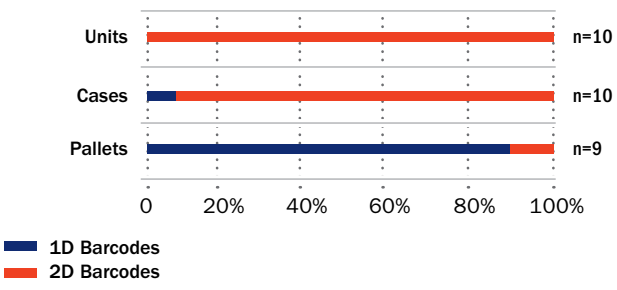
Radio Frequency Identification (RFID) Tags: Technology that passes data through radio waves.

Serialization Standards

Federal traceability legislation has now effectively codified FDA guidance on Serialized Numerical Identifiers[‡‡] (SNI). The SNI is a two-part series of characters consisting of the National Drug Code (NDC) and an alphanumeric serial number of up to 20 digits.

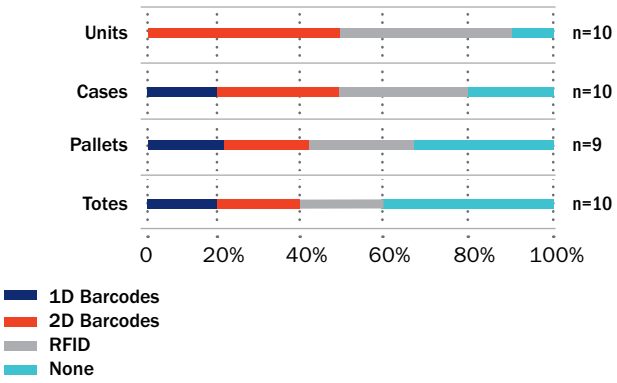
Seventy percent of manufacturers and 50 percent of wholesalers preferred to use the SNI serialization system despite the fact that the SNI was guidance rather than law when responses were collected. There was a similar pattern of preference for using GS1 standards, which exist for both serial number format and data transmission standards. Ninety percent of manufacturers and 60 percent of wholesalers prefer using GS1 standards in general.

Exhibit 8 | Manufacturer Preferences for Carrier Technologies for the Application of Serial Numbers



Manufacturers rarely ship with totes. Most manufacturers reported they would not be likely to adopt any data carrier for totes.

Exhibit 9 | Wholesaler Preferences for Carrier Technologies for the Application of Serial Numbers

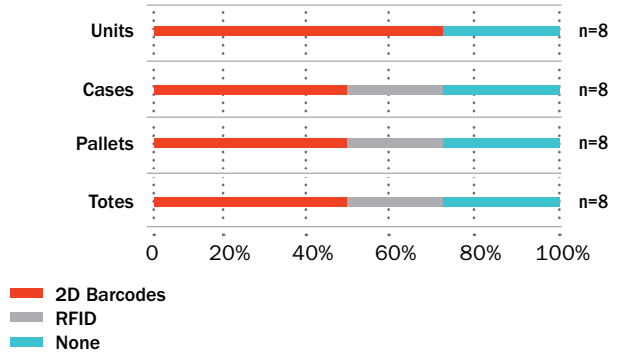


[††] A tote is a plastic container typically used to deliver medicines from a wholesaler to a dispenser.

[‡‡] Guidance for Industry–Standards for Securing the Drug Supply Chain–Standardized Numerical Identification for Prescription Drug Packages, Food and Drug Administration, March 2010.

[§§] See http://www.gs1.org

Exhibit 10 | Dispenser Preferences for Carrier Technologies for the Application of Serial Numbers



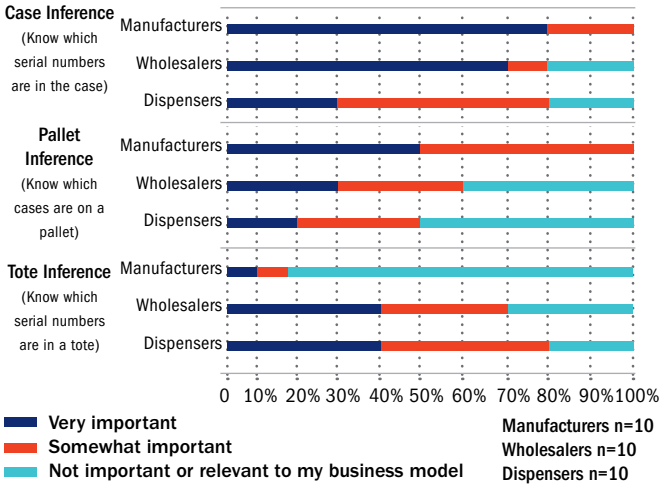
Federal legislation on a national traceability system now stipulates that manufacturers use 2D barcodes to affix serial numbers at the unit level, and either 1D or 2D barcodes at the case level. Responses to the questionnaire also suggested an industry trend in this direction for unit-level packages in advance of the law's passage, although sector preferences on other packaging levels were mixed (see Exhibits 8 to 10). Manufacturers said they would be most likely to use 2D barcodes for units and cases, 1D barcodes for pallets, and did not prefer RFID for any type of package. No wholesaler said they were likely to adopt 1D barcodes for unit-level packages—they appeared to equally prefer 2D barcodes and RFID instead. Most dispensers preferred 2D barcodes, with 25 percent of respondents preferring RFID for cases, pallets, and totes. Forty percent of wholesalers said they would not be likely to adopt any data carrier at the tote level, and 25 percent of dispenser respondents said the same for all packaging levels.

3.4.4 Inference and Aggregation

In a serialization and traceability system, inference is the ability to know which serialized packages are inside a case or other container without having to open it, and aggregation is the creation of serialized packaging hierarchy data to support inference (see Appendix D for a more detailed description of aggregation). Supply chain stakeholders who completed the questionnaire felt strongly about the importance of inference to the success of business processes. For all but one of the functionalities listed in Exhibit 11 below more than 70 percent of respondents identified inference as either required or very helpful. Inference was most important to efficient receiving business processes—87 percent of respondents said inference was required or very helpful for this function.

Exhibit 11 | Supply Chain Stakeholder Views on the Need for Inference for Specific Functions in a Serialization and Traceability System

Exhibit 12 | Supply Chain Stakeholder Views on the Importance of Inference at Various Container Levels



Stakeholder views on the importance of inference for various container types tended to vary (Exhibit 12). Case inference—knowing which serialized drug units have been packed in a case—was seen as very important by most manufacturers and wholesalers (80 percent and 70 percent respectively). Tote inference was the most important to dispensers and wholesalers, although less than half of each group—40 percent—thought it was very important. Pallet inference was the most relevant to manufacturers, with half of them marking it as very important. A pallet holds multiple cases, and is the highest level of container used in this supply chain.

While respondents agreed that inference is important for efficiency in a variety of business functions, the technology to enable inference—aggregation—was a concern for some, particularly regarding the potential for data errors to result in process interruptions. Fifty percent of manufacturers and wholesalers were very concerned about the quality or accuracy of the aggregation data that they would either produce or receive from trading partners. Thirty percent of dispensers were very concerned about aggregation data quality. Although manufacturers said they were not concerned about their ability to aggregate products, they worried about the ramifications for supply flow when errors in aggregation data occur. Apprehension around aggregation data quality also surfaced in follow-up interviews.

4. Manufacturer Implementation and Costs

4. Manufacturer Implementation and Costs

As described in detail in Section 2, cost estimates for serialization and traceability systems were collected directly from supply chain stakeholders, as well as from vendors that can be contracted to develop, integrate, and implement elements of or an entire serialization and traceability system. In this section, cost estimates from both manufacturers and vendors are presented, and variations between and within the groups are explored.

Although lack of clarity on regulatory expectations was a potentially complicating factor, industry stakeholders and vendors were better able to estimate the serialization and traceability systems' costs for manufacturers than for other sectors. In general, manufacturers have made more progress than their trading partners: many manufacturers are currently in the process of implementing serialization and traceability systems, while most wholesalers and dispensers are considering or have no plans for implementation. This is particularly true for regionally focused wholesalers who may not have encountered state serialization and traceability requirements.

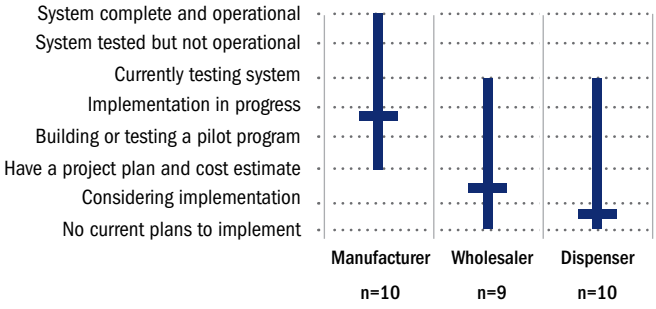
4.1 Implementation Status

4.1.1 Manufacturer Implementation Progress Compared to Other Supply Chain Sectors

The manufacturers in this study are establishing serialization and traceability systems more actively than wholesalers and dispensers, with 60 percent indicating that implementation is in process (Exhibit 13). By comparison, only one wholesaler and one dispenser reported they were currently implementing. Thirty-three percent of wholesalers and 60 percent of dispensers responding to this question said they have no current implementation plans.

Greater progress by manufacturers is most likely due to the early regulatory requirements for their sector under California's former electronic pedigree law, which were set to begin in 2015. In addition, the California law did not affect a number of wholesalers and many pharmacies in the U.S. Federal legislation now places implementation requirements on all sectors in the drug distribution supply chain; however these differ from the California law's requirements and are

Exhibit 13 | Progress Toward System Implementation for Manufacturers, Wholesalers, and Dispensers



The vertical blue bars show the range of implementation status for the three supply chain sectors, with the horizontal blue bars indicating the average status of the respective sectors.

phased-in over a longer time period. Manufacturers must serialize individual drug packages four years following enactment (late 2017), and wholesalers and dispensers must accept only serialized products six and seven years following enactment (late 2019 and 2020 respectively). An electronic system capable of tracing each package of drugs is not required until ten years after enactment (late 2023).

Manufacturers responding to this study appear well-positioned to meet these requirements. Eighty percent of manufacturers stated that they have a modern enterprise resource planning (ERP) system that, with appropriate add-on software, is fully capable of meeting the demands of a serialization and traceability system. Only 20 percent of wholesalers—and no dispensers—indicated this. Fifty-five percent of dispenser respondents indicated that they have a legacy ERP system and depend on custom programming to maintain it. This suggests that wholesalers and dispensers may have further to go, although they have longer time lines for compliance. Forty percent of manufacturers also indicated that they have sufficient data storage and communications capacity to manage a traceability system—two times as many as wholesalers and dispensers.

4.1.2 System Functionality Being Implemented by Manufacturers

Supply chain stakeholders were asked to indicate which functions are included, planned, or being considered for serialization and traceability systems. Similar to the overall implementation status by sector, manufacturers reported having many more features in place or planned than either wholesalers or dispensing organizations (see Exhibit 14).

4.2 Manufacturer Costs

Seven manufacturers provided cost estimates for a serialization and traceability system. These companies vary in size: five have 10 to 20 packaging lines, one operates fewer than 10 lines, and one has more than 30 lines. The number of cases of drugs shipped per month by these companies ranged from approximately 30,000 to 425,000.

Seven technology vendors also provided estimates for costs borne by a manufacturer. The vendors include companies that provide serialization equipment, data management technologies, and consulting services for overall strategy and vendor selection (see “Vendor Participants" on pg. 32).

For both sets of estimates, the study looked at total costs for system implementation and total annual recurring costs, as well as costs at different operational levels—including per packaging line, per site, and per enterprise (costs assessed for the organization as a whole, as opposed to more granularly).

Vendors were asked to provide costs for a hypothetical medium manufacturer with four packaging locations—each with three packaging lines—as well as two distribution centers. Estimates provided by manufacturers for their own costs were standardized by multiplying their reported per-line and per-site figures by the number of each for the hypothetical medium manufacturer. This calculation resulted in a series of theoretical total expenses, each based on an individual set of actual manufacturer-estimated figures.

Data provided by manufacturers and vendors yielded several high-level figures of interest:

- Based on manufacturer-provided data, the average total implementation cost for a hypothetical medium-sized company was $36 million. Based on vendor estimates, the average total implementation cost was $9.7 million.

Exhibit 14 | Percentage of Manufacturers Reporting Features either Included or Planned in Their Traceability Systems (Sum of Included and Planned)

Reported Feature	Manufacturers n=10
Serialization	
· Units	100%
· Cases	100%
· Pallets	70%
Aggregation	
· Units to Cases	90%
· Cases to Pallets	70%
Enable Inference of Pallet and Case Contents	90%
Chain of Custody	
· “One Up, One Back”	50%
· Full Chain of Custody	40%
· e-Pedigree	60%

- Major differences in cost estimates provided by manufacturers and vendors can be found in significantly larger enterprise-level expenditures reported by manufacturers.

- Manufacturers reported a wide range of actual costs per line, per site, and per enterprise. The per-line cost ranged from $400,000 to $2.8 million, with an average of $1.4 million. This variance is likely driven by differences in business models and the use of high-speed automated equipment.

- Only one manufacturer quantified savings resulting from a serialization or traceability system. They estimated $700,000 per year in reduced costs related to chargebacks.***

4.2.1 Total Average Costs for a Medium-Sized Manufacturer Reported by the Manufacturing Sector and Vendors

Exhibit 15 shows average implementation and annual ongoing costs for a medium-sized manufacturer, based on manufacturer-provided and vendor-provided estimates from those able to estimate comprehensive costs.

Average costs based on vendor estimates were significantly lower than those based on estimates from actual manufacturers. The biggest differentiator for implementation

*** A chargeback is a charge from a wholesaler to a manufacturer to compensate the wholesaler when it must sell product at a lower price than their purchase price, typically to accommodate a manufacturer’s contract arrangements with the end-buyer, such as a hospital or pharmacy.

costs appears to be major enterprise-level expenses reported by manufacturers that vendor estimates did not reflect. No vendor gave enterprise-level costs of more than $1.5 million, but three of seven manufacturers reported enterprise costs of $20 million or more. One potential explanation for the difference is that supply chain stakeholders are accounting for enterprise-level business expenditures—such as the cost of fully integrating new electronic capabilities into a company's existing data systems—that vendors, as service providers, do not typically capture. These also are likely different depending on individual company needs and business decisions. In a follow-up interview, for example, one manufacturer indicated its enterprise-level cost estimate covered systems of record—a company's master data set—as well as the cost of establishing software connections with outside organizations. In addition, vendor estimates did not include any internal labor costs for manufacturers; which, as reported by that sector, were a significant component of annual ongoing expenses. These differences limit the study's ability to directly compare cost estimates between supply chain stakeholders and vendors.

4.2.2 Costs Reported by the Manufacturing Sector

As noted above, estimates provided by manufacturers were themselves also wide-ranging, driven in part by the presence or absence of major enterprise-level expenditures, but also by differences in per-line and per-site costs. Exhibits 16 and 17 show estimated implementation and annual ongoing expenditures for a hypothetical medium manufacturer, based on cost data provided by manufacturer participants. Although seven respondents provided implementation estimates, only five offered estimates for ongoing costs. In addition to system costs, supply chain stakeholders were asked to quantify internal labor to implement and maintain serialization and traceability. Only five of the seven manufacturers broke out labor costs. Where provided, labor costs were generally a bigger portion of reported ongoing costs than of implementation costs. Types of incremental labor assessed included training, business process reengineering, and switching to a new product identification standard. See Appendix F for additional exhibits regarding labor cost estimates.

4.2.3 Manufacturing Sector Costs Reported by Vendors

Vendor estimates for manufacturers also varied (see Exhibit 18). Among consultancies estimating comprehensive costs

Exhibit 15 | Average Estimated Costs Standardized for a Medium Manufacturer

	Average Implementation Costs	Average Annual Ongoing Costs
Manufacturer-Provided Estimates	$36 million ($20 million–$48 million)	$7.2 million ($4.2 million–$9.7 million)
Vendor-Provided Estimates (From those able to estimate comprehensive costs – Vendors A, B and C)	$9.7 million ($6.4 million–$14 million)	$660,000 ($420,000–$1.1 million)

Average costs based on data provided by individual manufacturer and vendor respondents and standardized to a hypothetical medium-sized manufacturer consisting of four packaging sites, each with three packaging lines and two distribution centers. Combined costs at the line, site, and enterprise levels.

(Vendors A, B, and C), total implementation expenditures for a medium-sized manufacturer were $6.4, $8.5, and $14 million respectively (see Exhibit 18). The larger figure for Vendor C is mainly due to a higher cost estimate for aggregation technology than Vendors A and B (see section 4.4). Vendor D, which provides serialization and aggregation technologies, estimated these hardware and system costs for a medium manufacturer to be slightly more than $7 million. Vendors B and C were closely aligned in their estimates for annual ongoing costs at $420,000 and $440,000, while Vendor A's figure for a medium manufacturer was $1.1 million per year. In this case, Vendor A estimates higher annual expenses for ongoing operation of a company's local hardware and software systems.

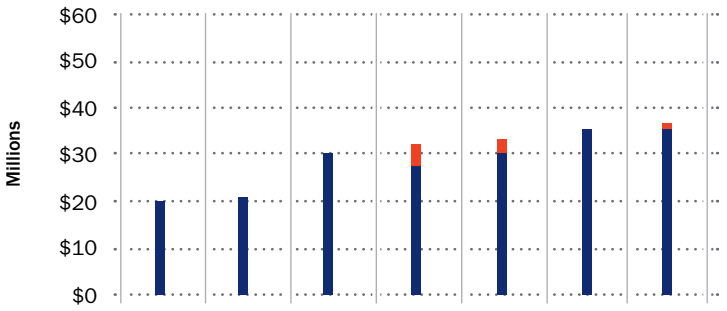
Cloud-based service providers (Vendors E, F, and G) estimated total implementation costs of $30,000 to $88,000 for their services. Of this group, Vendor F provided costs only to support data-sharing functionality, while estimates from Vendors E and G included cloud-based data support for additional serialization and traceability system components as well. For annual ongoing costs, Vendors E and G had closer estimates of $138,000 and $86,000 respectively, while Vendor F was higher at $650,000. Variation in these estimates is likely due to differences in the services covered by overall subscription costs.

Vendor Participants

Seven vendors, labeled "Vendor A" through "Vendor G," participated in this study. These vendors fall into three primary categories:

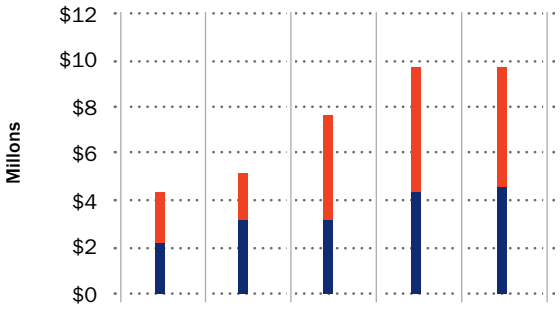
- Consultancies Estimating Comprehensive Costs (Vendors A, B, and C): These are consultancies of varying size that focus on developing serialization and traceability strategy, requirements, and vendor selection. Vendor B is the consulting arm of a larger developer of serialization line management software and systems.
  - These vendors attempted to include the cost of everything needed to implement solutions except the internal labor costs of their customers.
- Line Equipment Vendor (Vendor D): This is a manufacturer and integrator of pharmaceutical bottling line and packaging line equipment and systems.
  - Estimates from this vendor represent only a portion of total costs, but are significant components of serialization and aggregation functionality.
- Cloud-based Service Providers (Vendors E, F, and G): These are developers of cloud-based serialization and traceability data repository and exchange solutions.
  - Estimates supplied by these vendors cover their cloud-based service only. This service may be used to support multiple functionalities needed for a serialization and traceability system, but is not a comprehensive cost. For example, line-level packaging equipment is not included.

Exhibit 16 | Manufacturer Estimates for One-Time Implementation and Labor Costs Standardized for a Medium Manufacturer



Each implementation cost estimate is based on data provided by an individual manufacturer respondent and standardized to a hypothetical medium manufacturer consisting of four packaging sites, each with three packaging lines and two distribution centers. Combined costs at the line, site, and enterprise levels.

Exhibit 17 | Manufacturer Estimates for Annual Ongoing System and Labor Costs Standardized for a Medium Manufacturer



Each annual cost estimate is based on data provided by an individual manufacturer respondent and standardized to a hypothetical medium manufacturer consisting of four packaging sites, each with three packaging lines and two distribution centers. Combined costs at the line, site, and enterprise levels.

4.3 Line, Site, and Enterprise Costs

Significant variability in reported per-line expenditures explains part of the difference between manufacturer and vendor estimates. The average per-line cost provided by manufacturers was $1.4 million (ranging from under $500,000 to over $2.5 million), while the average vendor-provided costs per line were $320,000. Follow-up interviews clarified that these differences could be explained by business needs or technology choices; for example, some manufacturers with high-speed lines included costly, sophisticated automation equipment in their estimates. According to one vendor, a high-speed automatic case packer may cost $700,000.

Average site-level costs reported by these two groups were more similar. However, as discussed above, cost assessed at the enterprise level showed a broad gap between manufacturer and vendor estimates (see Exhibit 19). Enterprise-level expenditures reported by manufacturers ranged from under $2.5 million to more than $20 million, and were not adjusted before inclusion in the hypothetical medium-sized manufacturer totals. Variations in total enterprise costs could reflect business complexity, the need for more substantial upgrades to existing technology systems, or an estimation of costs to enable multiple software connections with trading partners, as was suggested during a follow-up interview.

Exhibit 18 | Vendor Estimates for Implementation and Ongoing Costs for a Medium Manufacturer

	Implementation Costs	Annual Ongoing Costs
Comprehensive Estimates		
Vendor A	$8.5 million	$1.1 million
Vendor B	$6.4 million	$420 million
Vendor C	$14 million	$440 million
Comprehensive Estimates		
Vendor D	$7.2 million	Not Provided
Comprehensive Estimates		
Vendor E	$88,000	$140,000
Vendor F	$30,000	$650,000
Vendor G	$45,000	$96,000

Estimates for a hypothetical medium-sized manufacturer consisting of four packaging sites, each with three packaging lines and two distribution centers. Combined equipment and services costs at the line, site, and enterprise levels.

Two other estimates of per-line costs in the public literature were examined for comparison, and both are generally lower than those estimates provided by manufacturer participants in this study. In 2012, the Generic Pharmaceutical Association estimated in comments to the California Board of Pharmacy that per-line costs for serialization and aggregation would be $750,000.[22] An analysis by Forrester in 2008 reported implementation costs of approximately $1.3 million per line; however this calculation also included portions of some site- and enterprise-level costs,[23] whereas figures in our study are cost incurred at the line-level alone.

Forrester also reported manufacturers' recurring costs as $130,000 per line, per year when 2D barcodes were the data carrier technology employed.[24] The manufacturer-reported costs in our study are higher, with reported annual ongoing costs per line for system upkeep and line-level labor averaging around $230,000.

4.4 Incremental Costs of Aggregation and Data Sharing

As discussed in Section 2, the study requested cost estimates based on four system components: serialization, local data, aggregation, and shared data (see Appendix D for more detailed descriptions). Many participants were unable to separate costs into these four discrete increments.

Exhibit 19 | Manufacturer and Vendor Estimates for Implementation Costs: Averages and Ranges per Line, Site, and Enterprise

	Average Cost Per Line	Average Cost Per Site	Average Enterprise Cost
Manufacturer-Provided Estimates	$1.4 million ($400,000–$2.8 million)	$980,000 ($120,000–$3.5 million)	$12 million ($2.4 million–$25 million)
Vendor-Provided Estimates (From those able to estimate comprehensive costs–Vendors A, B, and C)	$320,000 ($180,000–$490,000)	$720,000 ($400,000–$1.1 million)	$770,000 ($230,000–$1.4 million)

Site-level costs do not include expenses incurred at the line level. Similarly, enterprise-level costs do not include site-level or line-level expenses.

While some participants were able to estimate costs for aggregation and shared data components separately, costs for serialization and local data management were frequently provided as a single amount, reflecting business model realities for the responding stakeholders. Because of this, these elements were combined in the analysis.

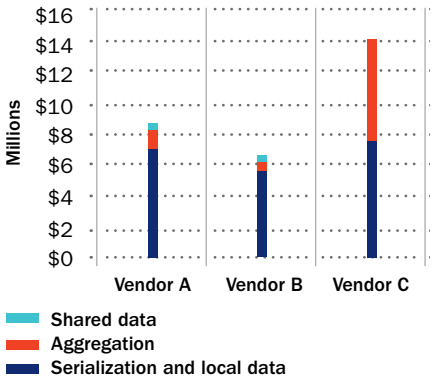
Vendors were generally better able to estimate costs by these system components than manufacturer participants. Vendor implementation cost estimates broken out by system components can be seen in Exhibit 20.

Aggregation

As discussed in section 3.4.4, supply chain stakeholders view aggregation, and the inference it supports, as essential to enable unit-level traceability–a system now required by federal legislation. Only four of the seven manufacturers were able to break out costs related to aggregation, and did so as a portion of costs per line. Based on these four estimates, aggregation averaged at $1.1 million per line, representing on average 65 percent of per-line costs. Actual costs ranged from $260,000 to $2 million.

Other per-line cost estimates for aggregation in the public literature are lower than the $1.1 million average. The Generic Pharmaceutical Association estimated incremental per-line cost for aggregation of $625,000; a line with serialization and aggregation was estimated to be $750,000, and a line with serialization alone would cost $125,000.[25]

Exhibit 20 | Vendor Estimates for Implementation Cost for a Medium Manufacturer Broken Out by System Components



Estimates for a hypothetical medium-sized manufacturer consisting of four packaging sites, each with three packaging lines and two distribution centers. Combined equipment and services costs at the line, site, and enterprise levels. Vendor C did not provide a broken-out cost for shared data.

Vendors were generally better able to break out the cost of aggregation than manufacturer participants; however because these estimates were based on different vendor service models they are presented here as a portion of overall costs rather than a portion of specific per-line costs. Total costs for aggregation for a medium-sized manufacturer (12 packaging lines, 4 sites, 2 distribution centers) from Vendors A, B, C (comprehensive costs), and Vendor D (line equipment) ranged from $570,000 to $6.6 million, with an average of $3.3 million. For vendors offering comprehensive cost estimates, aggregation was 23 percent of total costs on average, proportionally lower than the cost of serialization and local data management technologies.

Data Sharing

As with aggregation, not all manufacturers were able to separate out the cost of data sharing capacity. Three of seven manufacturers were able to estimate the incremental costs of data sharing at the enterprise level, ranging from $450,000 to $5 million. On average, shared data costs were about 20 percent of total enterprise-level implementation costs. Just two of the seven manufacturers estimated ongoing costs for data sharing, which were $150,000 and $300,000 per year.

Four vendors provided estimates for the incremental cost of data sharing as a portion of total costs for a medium-sized manufacturer. Vendors A and B provided comprehensive estimates, with implementation costs of $230,000 and $250,000–3 and 4 percent of total costs, respectively. Implementation estimates for cloud-based data sharing services were generally lower. Vendors A and B estimated annual ongoing costs at $39,000 and $48,000 per year (see Exhibit 21).

Exhibit 21 | Vendor Estimates for Incremental Cost of Data Sharing for a Medium Manufacturer

Vendors	Implementation Costs	Annual Ongoing Costs
Comprehensive Estimates		
Vendor A	$230,000	$48,000
Vendor B	$250,000	$39,000
Cloud-Based Data Service Only		
Vendor F	$30,000	$650,000
Vendor G	$20,000	$43,000

Combined costs at the line, site, and enterprise levels for a hypothetical medium-sized manufacturer consisting of four packaging sites, each with three packaging lines and two distribution centers.

5. Wholesaler and Dispenser Implementation and Costs

5. Wholesaler And Dispenser Implementation and Costs

Cost estimates for implementing and maintaining a serialization and traceability system were much less available for wholesalers and dispensers than for manufacturers. As noted previously, the wholesale and pharmacy participants in this study have less experience implementing technologies for a serialization and traceability system; as a result, their costs are not as well understood. Similarly, few vendors have direct experience working with these sectors.

Among the findings on wholesaler and dispenser costs:

- Three small wholesalers reported total implementation costs—including internal labor—of $44,000, $123,000, and $810,000
- Small wholesalers reported potential future annual benefits of $6,000 to $45,000 per year
- For vendors estimating comprehensive costs, theoretical expenditures for a large national wholesaler ranged from $3.1 million to $56 million for implementation, and $2.4 million to $13 million per year in ongoing costs
- Vendor estimates for a chain pharmacy were also theoretical, and ranged from $2.2 million to $28 million for system implementation
- Only one vendor estimated independent pharmacy costs; this estimate was for a cloud-based service, and anticipated $2,000 in implementation costs and $2,000 in annual ongoing costs

5.1 Wholesaler Costs

Four wholesalers provided cost estimates for participation in a national serialization and traceability system. Three of these were smaller wholesalers, shipping fewer than 10,000 packages or containers per month. A single large wholesaler, that ships more than 100,000 packages or containers per month, provided cost estimates, but these data are not presented at the request of the participant to ensure confidentiality.

Five vendors provided costs for the wholesale sector. Vendors were asked to estimate costs for a large national wholesaler with 28 distribution sites, each with seventeen stations for receiving, packing, and otherwise handling product.

Estimates provided by wholesalers were generally not broken out by system components or by different operational levels (such as per-site costs), but focused instead on total enterprise-level costs for a serialization and traceability system. Consequently, estimates could not be adjusted to the parameters of a hypothetical wholesale business. This limitation prevents a direct comparison between wholesaler and vendor estimates.

5.1.1 Costs Reported by the Wholesale Sector

Two smaller wholesalers provided similar estimated total expenses, one estimate based on perceptions and the other based on data from internal pilot programs. These wholesalers estimated total implementation costs—including incremental labor—of $123,000 and $44,000, respectively. Labor costs are responsible for most of the variation between these wholesalers. A third wholesaler, the smallest of the three businesses, reported perceived implementation costs of more than $800,000—almost an order of magnitude larger than the others (Exhibit 22). Estimates for ongoing costs were $199,000, $40,000, and $280,000 per year, including labor (Exhibit 23).

These three wholesalers also estimated the value of business benefits resulting from a serialization and traceability system—something most other supply chain respondents did not do (Exhibit 24). Reduced costs related to recalls were seen as valuable, a perspective echoed in follow-up interviews. In addition, one small wholesaler suggested in interviews that improved inventory management would provide the largest benefit generated by a serialization and traceability system.

Exhibit 22 | Small Wholesaler Estimates for One-Time Implementation and Labor Costs

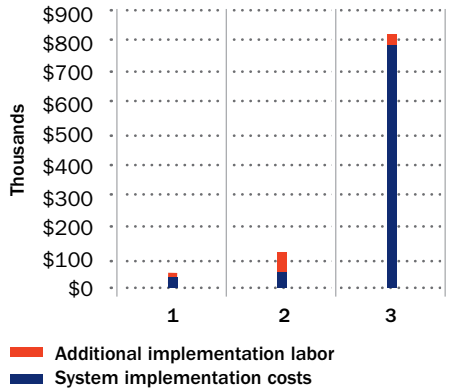
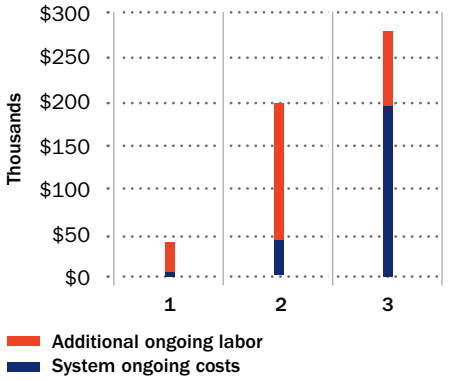


Exhibit 23 | Small Wholesaler Estimates for Annual Ongoing Costs and Additional Ongoing Labor



5.1.2 Wholesale Sector Costs Reported by Vendors

Five vendors provided cost estimates for a large-size wholesaler with 28 distribution centers nationwide, each with 17 stations for receiving, packing, and otherwise handling product (Exhibits 25 and 26). Cost estimates from Vendors A, B, and C—consultancies estimating comprehensive costs—ranged fairly widely, from $3.1 million to $56 million in implementation costs and $2.4 million per year to $13 million per year in ongoing costs. Vendor C's significantly higher figures include higher per-site costs for software and hardware than those estimated by Vendors A and B. These variations are most likely driven by differences in business models and lack of direct experience with this sector; which, in turn, affects the ability of vendors to offer confident and well-characterized estimates.

Two vendors providing cloud-based data management also shared estimates for these services for a large wholesaler. They estimated $30,000 and $70,000 for implementation and $83,000 and $600,000 for annual ongoing costs.

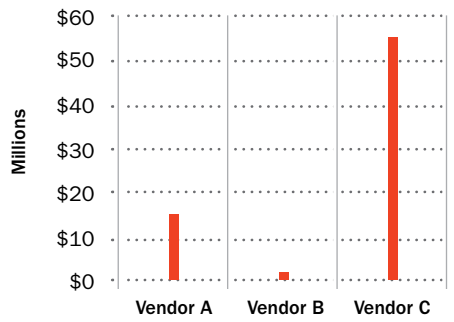
5.2 Dispenser Costs

Of the 11 pharmaceutical dispensers that participated in the questionnaire, only one—a mail-order pharmacy—provided cost information. This data was excluded from the analysis to protect respondent confidentiality.

Exhibit 24 | Small Wholesaler Perceived Annual Value of Benefits of a Serialization and Traceability System

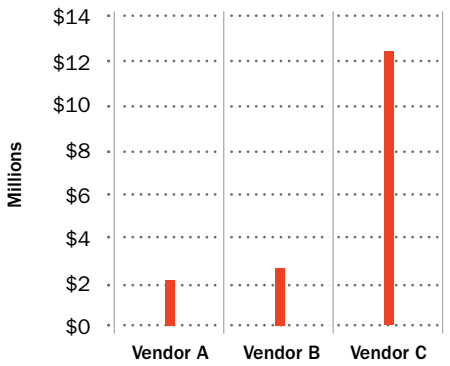
	Wholesaler 1	Wholesaler 2	Wholesaler 3
Reduce costs and improve efficiencies related to recalls	$15,000	$30,000	$1,000
Improve inventory or materials management			$1,000
Improve procurement and invoicing automation		$5,000	$1,000
Improve supply chain visibility	$20,000		$1,000
Reduce costs related to chargebacks			$1,000
Reduce costs related to returns	$10,000		$1,000
Total	$45,000	$35,000	$6,000

Exhibit 25 | Vendor Estimates for One-Time Implementation Costs for a Large Wholesaler



Combined equipment and services costs for a hypothetical wholesaler consisting of 28 distribution centers, each with 17 stations.

Exhibit 26 | Vendor Estimates for Annual Ongoing Costs for a Large Wholesaler



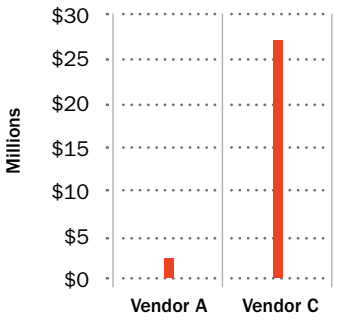
Combined equipment and services costs for a hypothetical wholesaler consisting of 28 distribution centers, each with 17 stations.

No vendor was able to base cost information on direct experience with pharmacies to implement a serialization and traceability system. Based on their business models and experiences with other sectors, however, two vendors offered estimated system costs for a hypothetical large chain pharmacy consisting of 14 distribution centers and 4,000 pharmacy retail stores. The two implementation cost estimates were $2.1 million and $28 million (Exhibit 27). As with vendor estimates for wholesalers, the large difference in these figures is likely due to the lack of actual implementation experience with the sector, as well as differences in vendor service models. Only one consultancy, Vendor C, provided an annual ongoing cost estimate for a large chain pharmacy, which was $12.6 million.

Vendor F also provided cost estimates for their cloud-based service for the hypothetical large chain pharmacy. These amounted to $833,000 for implementation and $2 million annually, which covered data sharing only.

Vendors were also asked to assess the costs borne by independent pharmacies, which the questionnaire defined as a single pharmacy store. Vendor F provided cost estimates for their cloud-based service, which would allow the independent pharmacy to store all of its local and shared data in a single repository, plus a single barcode reader. Their estimate amounted to $2,000 in implementation costs and $2,000 in annual costs. Some vendors also indicated

Exhibit 27 | Vendor Estimates for One-Time Implementation Costs for a Large Chain Pharmacy



Combined equipment and services costs for hypothetical chain pharmacy consisting of 14 distribution centers and 4,000 pharmacies.

in their interviews that they expect some wholesalers will provide serialization and traceability services to small pharmacies as part of their service offering and business agreement. In these cases independent pharmacies would rely on wholesalers to manage the local and shared data required for participation in a national serialization and traceability system.

These estimates for dispensers are significantly lower than a set of public cost estimates released by consulting firm Accenture in 2008. The highest vendor estimate in our study for a chain pharmacy to implement serialization and traceability is $28 million. In the Accenture report, however, implementation costs for a chain pharmacy of the same size were estimated at just under $495 million. For a single independent pharmacy Accenture estimated approximately $80,000 in implementation costs for a pharmacy store and $30,000 for a pharmacy data center;[26] the one estimate in our study put implementation costs at $2,000.

These figures were calculated in different ways and include different elements, however, and consequently are not directly comparable. Internal labor costs are included in Accenture's figures, for example, but not in the vendor estimates presented here.

For additional context it is worth noting two other specific differences. First, the Accenture report did not consider technologies such as cloud computing to support serialization and traceability. As Accenture notes, a cloud–based service would likely assess a regular usage fee, and could allow users to avoid up-front hardware and software investments.[27] Estimates in our study from Vendors E, F, and G offer insights into theoretical pricing for cloud-based models.

Second, Accenture's figures assume that some drugs will be serialized using radio frequency identification (RFID) tags, which would require investments in two discrete technologies. This study assumes that serial numbers will be embedded in 2D barcodes, the current industry trend and current requirement for individual packages of medicine under federal law. Hardware to process RFID tags is significantly more expensive than hardware needed to handle 2D barcodes, and hardware costs comprise about 70 percent of the total implementation cost for a chain pharmacy in Accenture's estimates.[28]

6. Implementation Challenges and Benefits

6. Implementation Challenges and Benefits

6.1 Challenges

6.1.1 Internal and External Barriers to Implementation

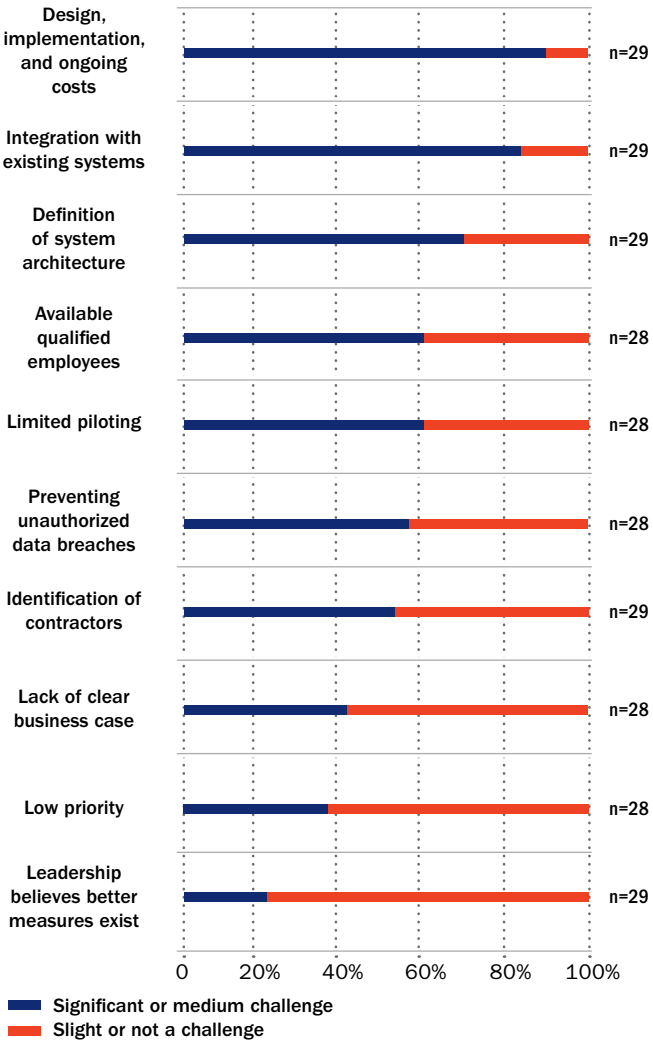
An effective serialization and traceability system relies on modifications to multiple existing systems and business processes. Implementation is a significant undertaking, and organizations in the supply chain anticipate both internal and external challenges.

According to questionnaire responses, the two most difficult internal challenges to overcome for all sectors were the integration of new technologies with existing systems and cost. Seventy percent of manufacturers and wholesalers said that system integration was a significant challenge, as did nearly 70 percent of dispensers. Cost was identified as a significant challenge by more than 50 percent of manufacturers, wholesalers, and dispensers. When asked to identify the single most challenging internal barrier the majority of wholesalers and dispensers chose cost; manufacturers did not align as a group. Dispensers noted significant challenges more frequently overall than respondents from other sectors.

Lack of buy-in from company leadership and low prioritization of a serialization and traceability system were much less likely to be seen as challenges than the issues mentioned above. Only one respondent felt that leadership support was a significant challenge. See Exhibit 28 for the results of all internal challenges listed in the questionnaire.

External challenges were viewed as more difficult to overcome than internal challenges (Exhibit 29). Lack of clear requirements and standards, as well as coordination with supply chain partners, were all seen as significant or moderate challenges by at least 80 percent of respondents. When asked to name the most difficult external barrier, 43 percent of respondents chose either a lack of clear regulatory requirements or a lack of immediate regulatory mandates. This was driven mainly by responses from manufacturers and wholesalers. The establishment of a national standard for serialization and traceability will help address some concerns related to regulatory expectations and timing, as discussed in Section 3.3.1. Certain important system elements, such as standards for managing and exchanging data between trading partners, must still be developed in the near future.

Exhibit 28 | Internal Challenges to the Implementation of a Serialization and Traceability System—All Sectors



Compliance with multiple countries' requirements was least often marked as a challenge, but was still seen as an obstacle by many respondents. Some manufacturers commented in interviews that countries and regions such as the EU, Turkey, China, and Argentina each have unique laws and implementation time lines that differ not only from each other's requirements, but from those in the U.S. Compliance with each set of laws draws on the same resources, employees, and contractors.

Exhibit 29 | External Challenges to the Implementation of a Serialization and Traceability System—All Sectors

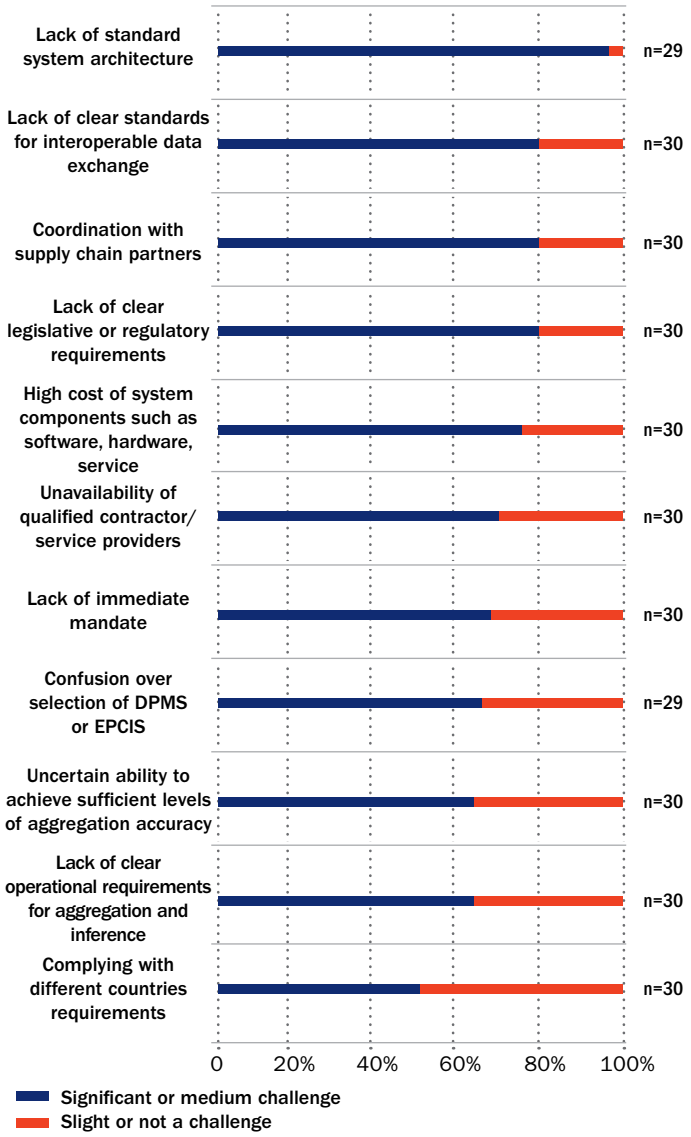
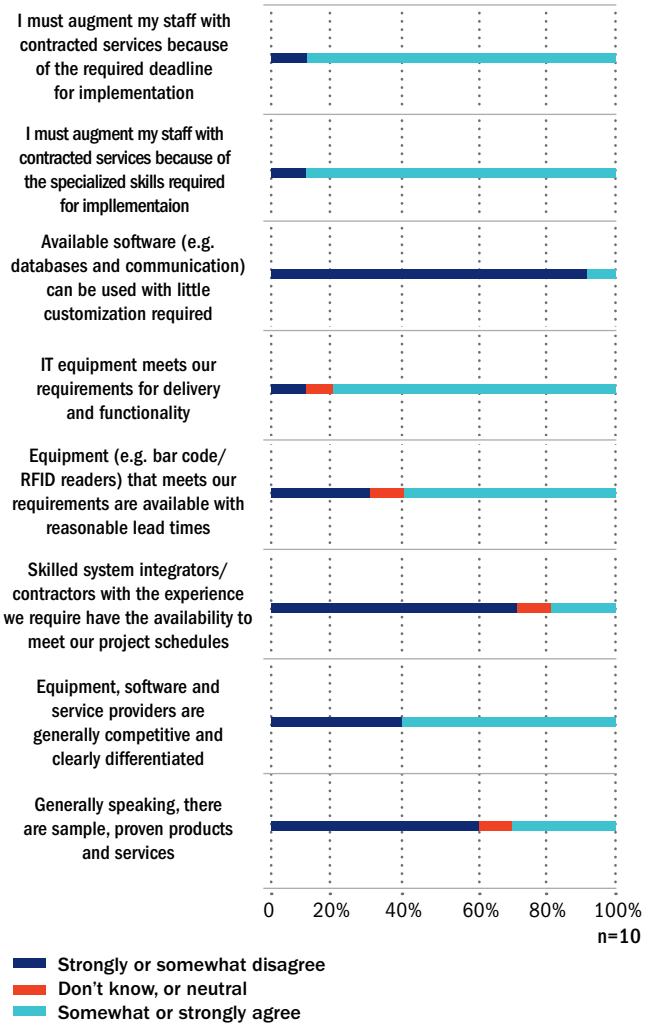


Exhibit 30 | Manufacturer Perspectives on the Availability or Sufficiency of Contracted Services to Implement Serialization and Traceability Systems



Respondents were also asked to estimate the impact of serialization and traceability systems on the speed of processes such as filling and labeling drug packages, receiving products into inventory, and packing and shipping products. Manufacturer respondents generally expected a negative impact on process speed: only 12 percent anticipated speed increases throughout all instances where manufacturers indicated a process speed change, while 78 percent anticipated a decrease. Wholesalers and pharmacies were less aligned, and several reported they could not estimate the potential impact on various process speeds.

6.1.2 Internal and External Capacity Needs—Availability of the Solution Provider Industry

Manufacturers, wholesalers, and dispensers expressed a range of expectations regarding employing internal or external resources to reach their implementation goals. Fifty percent of manufacturers plan to outsource most or all systems development and implementation, while only 20 percent say this work will be done by company staff. Conversely, 45 percent of responding dispensing organizations plan for implementation work to be done in-house. Ninety percent of

manufacturers, 50 percent of wholesalers, and 70 percent of dispensers agreed that they would have to augment their workforce to implement a system.

Although many manufacturers reported intent to outsource systems development, most were not confident that contractors with the required skills and experience would be available to meet implementation project time lines. Only 30 percent of manufacturers felt that the necessary products and services were available to them. In general, manufacturers had clearer opinions on vendor availability and sufficiency than wholesalers and dispensers, who more frequently reported that they did not know or were neutral.

Ninety percent of manufacturers and 50 percent of wholesalers expect to purchase mostly "off-the-shelf" commercial software, yet anticipate some customization based on the needs of their individual businesses. Manufacturers were less confident that any necessary software could be purchased or licensed as-is. Although vendor availability was generally a concern, many manufacturers agreed that the non-IT equipment needed to implement a serialization and traceability system is sufficiently available.

Finally, sector respondents expressed different views on the degree of internal process changes needed to implement a traceability system. Ninety percent of manufacturers responded that successful system implementation will require a significant level of business process reengineering, while only 40 percent of respondents from the wholesale sector believe significant process reengineering will be needed.

6.1.3 Data Protection

Successfully sharing information is fundamental to the operation of a national traceability system, yet is a source of concern for many industry members. The majority of respondents were confident in the security of their own information systems, but many expressed reservations about having proprietary data transmitted to and stored on systems outside of their control. Some findings of interest related to data protection and quality include:

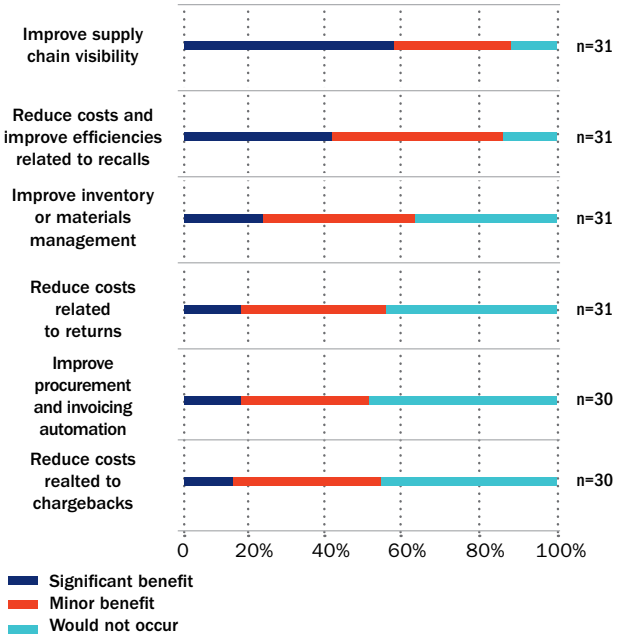
- 50 percent of respondents from each sector were very concerned about the potential for illegal breaches of information, while 30 to 40 percent were somewhat concerned
- 70 percent of wholesalers, 60 percent of dispensers, and 50 percent of manufacturers were very concerned about the ability to prevent trading partners from accessing proprietary information
- 60 percent of wholesalers were very concerned that operations would be slowed due to late-arriving or inaccessible data; 30 percent were somewhat concerned
- As mentioned above, 50 percent of manufacturers and wholesalers were very concerned about the quality or accuracy of aggregation data they would either produce or receive, while only 30 percent of dispensers were very concerned about aggregation data quality

Sixty-three percent of questionnaire respondents reported that they were very concerned about managing errors and exceptions generated by traceability systems. Interviewees worried about the impact that incorrect or late-arriving information might have on product logistics, and some commented that drug shortages might be exacerbated if product was quarantined due to data errors. Thirty-seven percent of all respondents were very concerned that drug shortages could result from poor quality traceability data.

6.2 Benefits

While regulatory compliance was a major motivation for system implementation, nearly all questionnaire respondents also cited the potential for additional benefit in one or more

Exhibit 31 | Perceptions of Business Benefits Gained from a Serialization and Traceability System



business areas; in particular, for improved supply chain visibility and more efficient recall processes. During follow-up interviews, a number of interviewees emphasized that any such benefits would likely be realized in the long term versus the short term, and that it is difficult to anticipate or quantify benefits at this time. Participants affirmed that the potential for business benefits was not driving investments, and that the goal of serialization and traceability systems was to better protect patients from counterfeit or compromised pharmaceutical product.

Eighty-seven percent of respondents listed improved supply chain visibility as a benefit—58 percent said it would be a significant benefit and 29 percent indicated a minor benefit. Eighty-four percent of respondents identified improvements to the recall process as a benefit, and half of those thought this benefit would be significant. For all other system improvements listed at least half of the respondents said they might see some degree of benefit, although a majority viewed these benefits as minor.

Overall, pharmaceutical manufacturers and dispensers who completed the questionnaire anticipated more benefits than wholesalers. Wholesalers anticipated improvements to recall efficiency as the area with the most potential benefit, with two anticipating a significant benefit and six anticipating a minor benefit in this area.

A number of manufacturers commented in their follow-up interviews that while increased supply chain visibility was desirable, an existing reluctance among supply chain partners to share information on product movement would be a hurdle to achieving this benefit. Although dispenser responses to the questionnaire indicated some anticipation for increased supply chain visibility, retail pharmacies have elsewhere emphasized the desire to protect proprietary data in order to preserve its confidentiality and commercial value.[29]

Although not emphasized in responses to the questionnaire, several respondents also suggested during interviews that a serialized system might permit more granular accounting for reverse payments in the supply chain, including: reimbursement for returned products, chargebacks, and rebates.††† This accounting improvement would be achieved by the seller's ability to identify exactly what product had been provided to a given supply chain partner, thereby ensuring that the corresponding claim for compensatory payment was accurate and appropriate.

Another topic explored in follow-up interviews was the potential role of public and private insurers in a national serialization and traceability system. Interviewees suggested a number of future benefits, including the potential authentication of serial numbers as a pre-condition of reimbursement by health care payment systems, similar to current requirements in countries such as Turkey and Italy. Additional suggested benefits for public and private insurers—and the health care delivery system in general—included the potential for reducing insurance fraud, the ability to improve medication adherence for patients, and improved ability to meet the reporting requirements of the Risk Evaluation and Mitigation Strategies (REMS) program established by the FDA as a condition of market approval.

††† Pharmaceutical manufacturers typically pay rebates for covered outpatient drugs reimbursed under state Medicaid programs.

7. Conclusion

7. Conclusion

This report provides a cross-sector snapshot of supply chain stakeholder preferences and estimated costs for pharmaceutical traceability systems. As previously stated, this information was gathered in early 2013—several months prior to the establishment of a national serialization and traceability standard. Following passage of the Drug Quality and Security Act, some shifts in stakeholder views and implementation plans are to be expected. The federal law will mean adjustments for companies that had already begun work toward meeting requirements set by the state of California, and will engender new activity for pharmacies and small wholesalers operating outside of California.

Although a new national law is now in place implementation remains a challenge, and work must still be done in all sectors to achieve full compliance.

Respondents to this study underscored the importance of regulatory clarity to permit stakeholders to adopt viable technologies, plan investments, and ensure systems can be adequately tested to prevent supply disruptions. Early development of important implementing guidance by the FDA, such as data exchange protocols, will be critical.

A uniform approach to storing and transmitting data—whether through a distributed, semi-centralized, or centralized model—was not defined in the law. It is clear from the varied preferences expressed by participants, however, that greater effort on plans for data management is needed. While the FDA may play a role in these discussions, supply chain stakeholders must work together to identify solutions that will allow trading partners and regulators to access and share data as required by the statute.

Another key implementation question concerns aggregation and inference. Respondents agreed that inference—the ability to infer the serialized products inside a container without opening it—is an important tool within a serialization and traceability system and necessary for efficient operations. However, the technology to enable inference—aggregation—was a concern for some, particularly when considering the potential for data errors to cause process interruptions. The Drug Quality and Security Act lists aggregation and inference as subjects for pilot programs and public meetings to inform the interoperable, electronic unit-level system launching in 2023. Supply chain stakeholders should also work with each other to test aggregation and inference systems.

This study found that while certain system requirements remain to be determined, manufacturers were further along in preparations to enable compliance with the law than other supply chain sectors. Many, in fact, are already implementing serialization systems. The variability of estimates from wholesalers suggests that their costs are not as well understood as manufacturers' costs. The least amount of data was available for the pharmacy sector: 60 percent of pharmacies responding to the questionnaire said that they do not currently have implementation plans in place. While staggered implementation dates reflect these differences in preparedness, supply chain actors will need to make implementation plans in the near future to ensure timely compliance.

The cost estimates presented in this study can offer a practical and high-level view of perceived investments necessary for compliance to stakeholders which are adjusting or initiating plans to meet U.S. traceability requirements. Manufacturing sector costs were better understood than those applicable to the wholesale or dispensing sectors. Within the set of manufacturer-provided estimates there was still notable variation, however, reflecting different business choices and some measure of uncertainty. Even those manufacturers that were actually implementing systems tended to perceive data sharing across the supply chain as a relatively new endeavor with associated unknowns. As with other technologies, it is possible that the cost of implementation will fall as the system becomes more standardized and universal.

Evolving and future models for traceability data management will likely include consideration of cloud-based data services. The study included cost estimates from three vendors currently providing cloud-based services for data management, which may prove helpful for stakeholders as they consider upcoming investment choices. One such estimate suggested that there may be significant low-cost options for independent pharmacies in particular. The Drug Quality and Security Act requires the FDA to commission an independent study to assess costs borne by pharmacies, which should include an examination of cloud-based service models for the pharmacy sector. The study should also explore the potential for wholesale suppliers to provide data management services for smaller, independent pharmacy clients.

Appendix A: Supply Chain Stakeholder Questionnaire

Serialization and Traceability Questionnaire

Introduction

Serialization and Traceability Questionnaire

There is currently no public analysis available on the cost to implement a national serialization and traceability structure for medicines across sectors in the U.S. pharmaceutical supply chain. Lawmakers are considering a federal standard to improve the security of drug distribution, but do not have credible system-wide, data-driven cost information to inform their deliberations. While companies are conducting internal analyses, the affected industry also lacks a cross-sector assessment of both cost and perceptions on various system features.

To remedy this information gap, Booz Allen Hamilton is working with The Pew Charitable Trusts to examine the economic dimensions of implementing a national serialization and traceability system for the U.S. pharmaceutical supply, specifically the pharmaceutical manufacturing, distribution, and retail/dispensing sectors.

We will explore cost drivers for specific system functionalities, the technical barriers to implementation, and the potential economic benefits generated by investment in serialization and traceability elements. We will also examine how the risk of counterfeit, stolen, and diverted medicines entering the legitimate pharmaceutical supply chain compares to other priorities and issues facing these sectors.

This questionnaire to stakeholders in the pharmaceutical manufacturing, distribution, and retail/dispensing sectors will be used to capture context, perceptions and opinions in the industry around system features, including estimated costs. Questions have been written to take this diversity of respondents into consideration, and we recognize and expect that some questions will not apply to all respondents.

We will also examine the economic dimensions of major system elements such as aggregation and standardized information exchange, through a separate cost model informed by in-depth interviews with technology providers and industry stakeholders. The questionnaire is organized as follows:

Section 1: Demographics
Section 2: Incentives and Disincentives to Implement Serialization and Traceability
Section 3: Serialization and Traceability Implementation: Functionality etc.
Section 4: Implementation and Recurring Costs
Section 5: Please tell us a little about yourself

We anticipate that the final report will be publicly available near the end of first quarter of 2013. Answers to the questionnaire will be non-attributable: nothing in our final report will be uniquely attributable to any respondent.

Serialization and Traceability Questionnaire

Instructions

This questionnaire is being issued to a broad audience of industry participants including manufacturers, distributors, regulators, and retail/dispensing organizations. By agreeing to complete this questionnaire you are providing valuable input to an effort to present how the issue of implementing a drug serialization and traceability system -- track and trace -- is being addressed by the U.S. pharmaceutical supply chain. Thank you in advance for your participation.

Please answer the questions from your company's/organization's point of view, and not from the view of your market segment or supply chain as a whole.

1. Complete all questions as requested.
2. Provide general comments where possible.
3. Please complete this questionnaire before 5:00 pm ET on Friday, February 15.

Definition of some terms used in the questionnaire:

Aggregation: Data that records exactly which packages are in the next largest package via serial numbers
Authentication: Ability to confirm that a serial number found on a given unit was produced by the manufacturer
COTS: Commercial Off The Shelf; a product available for purchase by the public
DPMS: Drug Pedigree Messaging Standard; a document-based GS1 standard that assists the pharmaceutical supply chain with creating an interoperable system to trace drugs in a way that can comply with existing document-based pedigree laws
EPCIS: Electronic Product Code Information Services; a general purpose GS1 standard designed to enable serial number related data capture and sharing within and across enterprises in supply chains
ERP: Enterprise Resource Planning; a software system used to manage many aspects of one's business
GTIN: Global Trade Identification Number; a GS1 standard for identifying a product class
Inference: Knowing which serial numbers are contained within a larger package by reading the larger package's serial number and using the Aggregation data supplied by the upstream trading partner
PCID: Physical-Chemical Identification
Serialization: Assigning a unique identifier (serial number) to a saleable package or logistical unit
System Architecture: Refers to a high-level map of traceability data storage and flow
Tote: A container typically used to transport a mix of units or small packages
Traceability: Ability to determine and document a package's distribution history throughout a supply chain
Unit-level: Refers to individual instances of the smallest saleable unit

Finally, please do not click the "exit survey" button at the top of the web form, as this will submit a response. To submit a completed response, please click the "complete" button at the end of the web form. Once complete, you will not be able to access the questionnaire to make changes. However, if cookies are enabled on your computer, you may close the browser window and later return to the questionnaire link where you should find your partial response saved.

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Serialization and Traceability Questionnaire

Organization Name

We need the name of your organization and your state for questionnaire verification purposes. This information will be removed before the questionnaire data are analyzed. Nothing in our final report will be uniquely attributable to any organization.

1. Please enter the name of your organization and your location.

Organization	
State in U.S.	

Serialization and Traceability Questionnaire

Demographics

2. How would you best describe your organization? Please select the main revenue sources from each of the primary and secondary columns.

	Primary pharmaceutical revenue source	Secondary pharmaceutical revenue source
Branded pharmaceutical manufacturer	◯	◯
Generic pharmaceutical manufacturer	◯	◯
Contract manufacturing or packaging	◯	◯
Wholesaler with national distribution	◯	◯
Regional wholesaler	◯	◯
National or regional pharmacy chain	◯	◯
Mail-order pharmacy	◯	◯
Local chain or independent pharmacy	◯	◯
Healthcare provider (e.g. hospital)	◯	◯

Other (please specify)

3. How many finished good pharmaceutical packages and other containers do you receive and ship in a MONTH for the U.S. market? Please estimate to one or two significant digits (e.g. 10,000 or 550,000). Enter a number or a range, and enter 0 if you do not receive or ship a specified package.

Smallest saleable packages (e.g. individual bottles) received	
Smallest saleable packages shipped	
Cases received	
Cases shipped	
Totes received	
Totes shipped	
Pallets received	
Pallets shipped	

Serialization and Traceability Questionnaire

4. Approximately how many lines or locations are used to package, distribute and/or sell your drugs to the U.S. market? Enter a number or a range, and enter "0" if you have none.

Number of your own packaging lines	
Number of third party contract packaging lines you make use of	
Number of your sites where packaging lines are located	
Number of your distribution centers from which product is shipped to customers	
Number of third party distribution centers under contract by you (3PLs)	
Number of your pharmacies	

Serialization and Traceability Questionnaire

Incentives and Disincentives to Implement Serialization and Traceability

The following several questions are to understand how important a serialization and traceability system is to your organization. For example, we ask for your perceptions around how counterfeiting, theft and diversion of drugs affect your organization. We also ask questions around the importance of perceived benefits of such a system.

5. If you have completed, are in process of, or planning to implement a serilization and traceability system, what were your organization's main motivations?

	Primary motivation	Secondary motivation	Not a motivation
Proactive approach to staying ahead of impending legislation (either state or federal)	◯	◯	◯
Compliance with existing regulations	◯	◯	◯
Proactive approach to preventing potential infiltration of counterfeit, stolen, or diverted product	◯	◯	◯
To gain greater supply chain information	◯	◯	◯
To harmonize business systems with trading partners	◯	◯	◯
Anticipated supply chain efficiencies.	◯	◯	◯

Other (please specify) or comments

6. How important is implementing a unit-level serialization and traceability system to your organization? This is:

- ◯ High priority
- ◯ Medium priority
- ◯ Low priority
- ◯ Not a priority

Comments

Serialization and Traceability Questionnaire

7. Which statements reflect why your organization would like to see a NATIONAL unit-level traceability system requirement? Select all that apply.

- [ ] Efforts to combat counterfeiting, theft, and diversion cannot be effective unless the tools include a national, unit-level traceability system.
- [ ] A national, unit-level traceability system is an important, but not critical, tool to combat counterfeiting, theft, and diversion.
- [ ] We need a single national system to replace the differing requirements of various state laws.
- [ ] A unit-level traceability system enables significant supply chain efficiencies.

Other (please specify)

8. Which statements reflect why your organization would NOT like to see a NATIONAL, unit-level traceability system requirement? Please select all that apply.

- [ ] Drug counterfeiting, theft, and diversion are not significant problems in the U.S. supply chain.
- [ ] There are more cost-effective methods to secure the drug supply chain than a national unit-level traceability system.
- [ ] There are too many ways to defeat or circumvent any protection that traceability would provide.
- [ ] Our operations are not national, therefore we do not need a national system.

Other (please specify)

Serialization and Traceability Questionnaire

9. How does your company perceive the threats to YOUR organization of drug counterfeiting, diversion, and theft in the US to have changed in the last 10 years? Please score by threat area.

Scorings are typified by:
Significantly decreasing: Used to require significant level of effort to control, but now much less effort is needed.
Slightly decreasing: We still need to be vigilant, but are less focused on these threats than before.
Neutral: We expend about the same level of effort to combat these threats as we did before.
Slightly increasing: We devote more attention and level of effort to combat these threats than before, but they are not in our top supply chain priorities.
Significantly increasing: We have needed to improve our mitigation processes because new threats constantly emerge.

	Significantly decreasing	Slightly decreasing	Neutral	Slightly increasing	Significantly increasing	Don't know
Introduction of counterfeit drugs in to the legitimate finished goods supply chain	◯	◯	◯	◯	◯	◯
Introduction of stolen drugs in to the legitimate finished goods supply chain	◯	◯	◯	◯	◯	◯
Introduction of diverted drugs, such as drugs that have already been dispensed, in to the legitimate finished goods supply chain	◯	◯	◯	◯	◯	◯
Introduction of counterfeit, stolen, or diverted drugs in to the legitimate supply chain through a returns process	◯	◯	◯	◯	◯	◯
Illegal "street" sales of pharmaceuticals	◯	◯	◯	◯	◯	◯
Internet sales of counterfeit drugs	◯	◯	◯	◯	◯	◯

Other (please specify)

Serialization and Traceability Questionnaire

10. Please indicate your current annual costs in units of thousands of U.S. Dollars ($K) for the categories below related to counterfeiting, theft and diversion. More than 2 significant digits is not necessary. Enter a number or a range. (For example, enter "550" to indicate $550,000, or "60-70" to indicate a range of $60,000 to $70,000.)

Anti-counterfeiting technologies (e.g. packaging, PCID)	
Cost to monitor and prosecute counterfeiting	
Logistics security	
Lost sales due to counterfeiting	
Losses due to diversion and theft	

11. For these same categories, please indicate how these costs would likely change annually for the next 2 years assuming a national unit-level traceability system DOES NOT become a requirement. Assume zero inflation-related cost changes for this question.

	>5% increase per year	1-5% increase per year	minor or no change	1-5% decrease per year	>5% decrease per year
Anti-counterfeiting technologies (e.g. packaging, PCID)	◯	◯	◯	◯	◯
Costs to monitor and prosecute counterfeiting	◯	◯	◯	◯	◯
Logistics security	◯	◯	◯	◯	◯
Lost sales due to counterfeiting	◯	◯	◯	◯	◯
Losses due to diversion and theft	◯	◯	◯	◯	◯

Comments or clarifications

Serialization and Traceability Questionnaire

12. Again for these same categories, please indicate how these costs would likely change annually for the next 2 years assuming a national unit-level traceability system DOES become a requirement. Assume zero inflation-related cost changes for this question.

	>5% increase per year	1-5% increase per year	minor or no change	1-5% decrease per year	>5% decrease per year
Anti-counterfeiting technologies (e.g. packaging, PCID)	◯	◯	◯	◯	◯
Costs to monitor and prosecute counterfeiting	◯	◯	◯	◯	◯
Logistics security	◯	◯	◯	◯	◯
Lost sales due to counterfeiting	◯	◯	◯	◯	◯
Losses due to diversion and theft	◯	◯	◯	◯	◯

Comments or clarifications

13. Referring to the above question, what are other cost categories for your organization related to counterfeit, stolen, or diverted drugs? Relatively how significant are they?

Serialization and Traceability Questionnaire

14. What INTERNAL challenges did or does your organization face with regards to implementing a pharmaceutical serialization and traceability system for the U.S. market?

	Not a challenge	Slight challenge	Medium challenge	Significant challenge
A) Definition of system architecture	◯	◯	◯	◯
B) Identification of business partners / service providers	◯	◯	◯	◯
C) Integration with existing systems	◯	◯	◯	◯
D) Preventing unauthorized data breaches	◯	◯	◯	◯
E) Cost of implementation and on-going operation (internal system and development costs)	◯	◯	◯	◯
F) Company leadership believes that better distribution security measures exist	◯	◯	◯	◯
G) Low priority inside my company	◯	◯	◯	◯
H) Lack of clear business case/financial constraints/low ROI	◯	◯	◯	◯
I) Limited amount of piloting work	◯	◯	◯	◯
J) Availability of qualified employees	◯	◯	◯	◯

Other (please specify) or comments

15. Referring to the previous question, which INTERNAL barrier to system implementation is the MOST difficult challenge to overcome?

◯ A ◯ B ◯ C ◯ D ◯ E ◯ F ◯ G ◯ H ◯ I ◯ J

Comments

Serialization and Traceability Questionnaire

16. What EXTERNAL challenges or factors have delayed or would delay your organization's implementation of a pharmaceutical serialization and traceability system for the U.S. market?

	Not a challenge	Slight challenge	Medium challenge	Significant challenge
A) Lack of clear legislative or regulatory requirements	◯	◯	◯	◯
B) Lack of immediate mandate	◯	◯	◯	◯
C) Lack of standard system architecture	◯	◯	◯	◯
D) High cost of system components such as software, hardware, service	◯	◯	◯	◯
E) Unavailability of qualified contractors/service providers	◯	◯	◯	◯
F) Coordination with supply chain partners	◯	◯	◯	◯
G) Lack of clear standards for interoperable data exchange	◯	◯	◯	◯
H) Confusion over selection of DPMS or EPCIS	◯	◯	◯	◯
I) Lack of clear operational requirements for aggregation and inference	◯	◯	◯	◯
J) Uncertain ability to achieve sufficient levels of aggregation accuracy	◯	◯	◯	◯
K) Complying with different countries' requirements	◯	◯	◯	◯

Other (please specify) or comments

17. Referring to the previous question, which EXTERNAL barrier to system implementation is the MOST difficult challenge to overcome?

◯ A ◯ B ◯ C ◯ D ◯ E ◯ F ◯ G ◯ H ◯ I ◯ J ◯ K

Comments

Serialization and Traceability Questionnaire

18. Some potential supply chain benefits of a national, unit-level serialization and traceability system -- beyond affecting the flow of counterfeit, stolen, and diverted drugs -- have been described.

Which additional benefits does your organization believe would result from implementing such a system?

Scoring descriptions are relative to not having such a traceability system, and are typified by:
Significant benefit: Could probably justify at least 10% of the cost of a system on an ROI basis alone
Minor benefit: Would be directionally improved, but would have a small affect on operating cost budgets
Would not occur: This benefit would not result from the implementation of a national unit-level serialization and traceability system

	Significant benefit	Minor benefit	Would not occur
Reduce costs and improve efficiencies related to recalls	◯	◯	◯
Improve inventory or materials management	◯	◯	◯
Improve procurement and invoicing automation	◯	◯	◯
Improve supply chain visibility	◯	◯	◯
Reduce costs related to chargebacks	◯	◯	◯
Reduce costs related to returns	◯	◯	◯

Serialization and Traceability Questionnaire

19. What impact will implementing a serialization and traceability system have on the operating speed and efficiency of your packaging and logistics processes?

	Improve >5%	Improve 1-5%	No change	Decrease 1-5%	Decrease >5%	Don't know or not applicable
Speed of filling and labeling smallest saleable units	◯	◯	◯	◯	◯	◯
Rate of proper rejection of incorrectly packaged or labeled units	◯	◯	◯	◯	◯	◯
Speed of filling and labeling cartons or pallets that contain mutiple smaller packages	◯	◯	◯	◯	◯	◯
Speed to receive a product in to inventory	◯	◯	◯	◯	◯	◯
Speed to pick, pack, and ship a product	◯	◯	◯	◯	◯	◯

Other efficiencies that may change

20. Which of the below would be affected by a national unit-level serialization and traceability system? Select all that apply.

	Improve	No impact	Make worse	Don't know
Improve public health by strenghtening the distribution system's ability to safeguard medicines	◯	◯	◯	◯
Prevent insertion of counterfeit drugs into the legitimate supply chain	◯	◯	◯	◯
Prevent reintroduction of stolen drugs into the legitimate supply chain	◯	◯	◯	◯
Prevent reintroduction of diverted drugs into the legitimate supply chain	◯	◯	◯	◯
Mitigate drug shortages	◯	◯	◯	◯
Increased data sharing across the supply chain	◯	◯	◯	◯

Indicate other aspects of patient safety that would be affected

Serialization and Traceability Questionnaire

21. Which of the following characteristics for a national standard are preferred by your organization? Select all that apply.

- [ ] A system that is implemented in increments over time.
- [ ] A system that ultimately results in unit-level authentication.
- [ ] A system that ultimately results in unit-level traceability.
- [ ] A single Federal standard instead of several varying state standards.
- [ ] All supply chain nodes should participate in a national traceability system, including manufacturers, wholesalers, and retailers/dispensing sectors (entities that purchase drugs to sell or dispense to patients).

Other (please specify)

Serialization and Traceability Questionnaire

22. What are your thoughts about the companies, products and services that are available to use for implementing serialization and traceability systems?

	Strongly agree	Somewhat agree	Neutral	Somewhat disagree	Strongly disagree	Don't know
Generally speaking, there are ample, proven products and services.	◯	◯	◯	◯	◯	◯
Equipment, software and service providers are generally competitive and clearly differentiated.	◯	◯	◯	◯	◯	◯
Skilled system integrators/contractors with the experience we require have the availability to meet our project schedules.	◯	◯	◯	◯	◯	◯
Equipment (e.g. bar code/RFID readers) that meets our requirements are available with reasonable lead times.	◯	◯	◯	◯	◯	◯
IT equipment meets our requirements for delivery and functionality.	◯	◯	◯	◯	◯	◯
Available software (e.g. databases and communication) can be used with little customization required.	◯	◯	◯	◯	◯	◯
I must augment my staff with contracted services because of the specialized knowledge and skills required to design and implement a serialization and traceability system.	◯	◯	◯	◯	◯	◯
I must augment my staff with contracted services because of the required deadline for implementing a serialization and traceability system.	◯	◯	◯	◯	◯	◯

Comments or clarifications

Serialization and Traceability Questionnaire

Serialization and Traceability Implementation: Functionality and Technolog...

This section of the questionnaire is about how a serialization and traceability system should perform, and your preferences for the underlying technology.

23. Have you implemented or are you planning to implement systems to support electronic traceability for serialized drug products?

- ◯ System is complete and operational
- ◯ System tested, but decided not to implement
- ◯ Currently testing the system
- ◯ Implementation is in process
- ◯ We are building and/or testing a pilot program
- ◯ Have a project plan and cost estimate
- ◯ Considering implementing
- ◯ No current plans to implement
- ◯ Not applicable

Other (please specify)

Serialization and Traceability Questionnaire

24. Which of the following capabilities or system attributes will or would be included in your serialization and traceability system? Select all that apply.

	Feature currently in place	Implementation planned	Capability included but not "turned on" at start	May consider for future implementation	Not included	Not aware this was possible	Don't know
Unit-level serialization	◯	◯	◯	◯	◯	◯	◯
Case-level serialization	◯	◯	◯	◯	◯	◯	◯
Pallet-level serialization	◯	◯	◯	◯	◯	◯	◯
Aggregation of units to cases	◯	◯	◯	◯	◯	◯	◯
Aggregation of cases to pallets	◯	◯	◯	◯	◯	◯	◯
Use of aggregation to infer contents of cases & pallets	◯	◯	◯	◯	◯	◯	◯
GS1 EPCIS-based system	◯	◯	◯	◯	◯	◯	◯
GS1 DPMS-based system	◯	◯	◯	◯	◯	◯	◯
Document chain of custody "one up and one back"	◯	◯	◯	◯	◯	◯	◯
Document full chain of custody	◯	◯	◯	◯	◯	◯	◯
e-Pedigree	◯	◯	◯	◯	◯	◯	◯
EDI (electronic data interchange)	◯	◯	◯	◯	◯	◯	◯
AS2 (secure data transfer standard)	◯	◯	◯	◯	◯	◯	◯

Other (please specify)

25. What serialization carrier technology would most likely be adopted by your company for traceability systems?

	1D bar code	2D bar code	RFID	None
Units	◯	◯	◯	◯
Cases	◯	◯	◯	◯
Pallets	◯	◯	◯	◯
Totes	◯	◯	◯	◯

Other data carrier technology (please specify)

Serialization and Traceability Questionnaire

26. What is your PREFERRED method of representing electronic traceability data across the supply chain?

- ◯ GS1 Drug Pedigree Messaging Standard (DPMS) based approach
- ◯ GS1 Electronic Product Code Information Service (EPCIS) based approach
- ◯ Both DPMS and EPCIS should be used
- ◯ No preference

Other (please specify) or comments

27. What system capability do you PREFER for drug authentication?

- ◯ Drug authentication by retail/dispensing sectors only (entities that purchase drugs to sell or dispense to patients)
- ◯ Drug authentication at all points in the supply chain
- ◯ None

Other (please specify) or comments

28. Which one of the following models reflects your organization's preference for storing and managing the traceability data that your company receives and generates?

- ◯ Distributed Model: Each organization stores its own data and is responsible for transmitting it, when required, in a standard format
- ◯ Semi-Centralized Model: Organizations transmit traceability data to one of a few or several databases that are managed by third parties
- ◯ Centralized Model: Organizations all transmit traceability data to a single repository which could be run by a public or private entity, and would likely be managed by the government or an industry consortium
- ◯ No preference

Comments

Serialization and Traceability Questionnaire

29. What additional preferences or plans does your company have for a serialization and traceability system? Select all that apply.

- [ ] Our company prefers a solution hosted by a third-party solution/service provider to store and transmit traceability data when required.
- [ ] Our company prefers a solution hosted by another trading partner in the supply chain to store and transmit traceability data when required.
- [ ] Our preferred system would or will reside in company-owned or operated databases.
- [ ] We would or will use a cloud-based system.
- [ ] We expect to interact with several independent systems.
- [ ] Our system will be integrated in to our ERP or inventory management system.
- [ ] Our system will be a stand-alone module and will communicate with other company systems.
- [ ] If there must be a national serialization and traceability system, we prefer a single type of system and a single set of standards used by all pharmaceutical supply chain partners.
- [ ] If there must be a national serialization and traceability system, we prefer one based on GS1 standards.
- [ ] If there must be a national serialization and traceability system, we prefer that the number of allowed serial number carrier technologies be limited and selected by some authority.
- [ ] If there must be a national serialization and traceability system, we prefer one that makes use of the standards established in the FDA's Standardized Numerical Identification (SNI) guidance.

Other (please specify)

Serialization and Traceability Questionnaire

30. Please select from the following list any concerns your company has regarding traceability data storage and communication. Check all that apply.

	Very concerned	Somewhat concerned	Not concerned
Data security and the potential for illegal breaches of information	◯	◯	◯
The ability to prevent other supply partners from accessing our proprietary information	◯	◯	◯
The number of data connections we may need to establish with our trading partners	◯	◯	◯
Quality/accuracy of the aggregation data we will produce/receive	◯	◯	◯
Operations will be slowed due to late-arriving or inaccessible data that will be needed	◯	◯	◯
The possibility of drug shortages caused by poor quality traceability, late or inaccessible data	◯	◯	◯
We may not have our systems ready in time for current mandates	◯	◯	◯
Trading partners may not have their systems ready in time for current mandates	◯	◯	◯
Ability of our systems to interoperate with those of our trading partners	◯	◯	◯
Providing full chain of custody for returned products	◯	◯	◯
Liability for data errors made by our trading partners	◯	◯	◯
Managing errors and exceptions	◯	◯	◯

Other (please specify)

Serialization and Traceability Questionnaire

31. How important to your business is the ability to infer the contents of a case, pallet or tote of pharmaceuticals for traceability purposes without opening it or breaking it down?

Choices are typified by:
Very important: Must be successful for us to achieve our objectives and derive maximum benefit from a traceability system
Somewhat: Assuming it's not required for regulatory compliance, implementation is desirable but optional

	Very important	Somewhat important	Not important or relevant to my business model
Case inference (know which serial numbers are in the case)	◯	◯	◯
Pallet inference (know which cases are on a pallet)	◯	◯	◯
Tote inference (know which serial numbers are in a tote)	◯	◯	◯

Other (please specify)

32. How would inference help or hinder the following functionalities?

	Inference required for this functionality	Inference very helpful	Inference helpful, but not necessary	Inference makes no difference	Inference hinders this functionality	Not relevant to my business model
Identify contained serial numbers without opening containers	◯	◯	◯	◯	◯	◯
Efficient shipping business process	◯	◯	◯	◯	◯	◯
Efficient receiving business process	◯	◯	◯	◯	◯	◯
Accurate data exchange with trading partners	◯	◯	◯	◯	◯	◯
Efficient case-packing and pallet building business process	◯	◯	◯	◯	◯	◯
Efficient pick/pack business process	◯	◯	◯	◯	◯	◯

Serialization and Traceability Questionnaire

33. Which statements best describe your organization's business or pharmacy management software and IT systems? Select all that apply.

- [ ] We have a modern ERP (enterprise resource planning) system that, with appropriate add-on software, is fully capable of meeting the demands of operating a unit-level serialization and traceability system.
- [ ] We have a legacy or custom-built system and depend on custom software code to maintain it.
- [ ] We have several independent systems for manufacturing, warehouse management, billing, etc.
- [ ] We have a commercial off the shelf system that cannot be customized.
- [ ] We have sufficient data storage and communications capacity to manage a unit-level traceability system.
- [ ] Our IT infrastructure will require significant upgrades in order to handle the demands of a unit-level traceability system.
- [ ] We currently have no business or pharmacy management software.
- [ ] We have already deployed a unit-level traceability system based on the GS1 EPCIS standard.
- [ ] We have already deployed a nuit-level traceability system based on the GS1 DPMS standard.

34. What resources are you using or will you use to implement your serialization and traceability system? Check all that apply.

- [ ] Entirely commercial off the shelf (COTS) software products
- [ ] Mostly COTS software with some customization
- [ ] Mostly or entirely customized software
- [ ] Development and implementation work will be mostly or entirely outsourced
- [ ] Development and implementation work will be mostly or entirely done by company staff
- [ ] Significant business process reengineering will be required
- [ ] We have no plans to implement a serialization and traceability system

Serialization and Traceability Questionnaire

Implementation and Recurring Costs

The next several questions capture the costs associated with a serialization and traceability system.

SPECIAL INSTRUCTIONS
Implementation and recurring costs are requested at the line, site, and enterprise levels. LINE-level costs are solely to support one particular packaging line, such as an individual piece of equipment. SITE-level costs are those that support all the lines on a site, such as servers or some software licenses. ENTERPRISE-level costs are those that serve the all applicable sites and the lines in them.

Some fields may be blank. For example, there may be no enterprise-level equipment expenses for serialization.

We also recognize that companies across sectors will have different cost profiles. If it is not possible to segregate costs in to each category, please choose a most appropriate category to enter a combined cost. Please then indicate in the comment field at the bottom of each category what these combined costs represent. For example, if you enter a cost representing both serialization and aggregation in the aggregation category, please indicate that this is the case.

Please input all costs in units of thousands of U.S. Dollars ($K). Input line-level costs on a per-line basis. Enter site-level costs on a per-site basis. Precision greater than two significant digits is not necessary (e.g. 430 or 2,700). Cost ranges are also acceptable. (For example, enter "550" to indicate $550,000, or "60-70" to indicate a range of $60,000 to $70,000.)

Implementation costs are broken up in to four categories:

Equipment and installation (cost to procure and install, e.g., printers, cameras, automatic rejection machines, etc.);
Engineering services (costs to design and specify anything needed for implementation);
Software (e.g. custom or off-the-shelf); and
Other

Similarly, recurring costs are also broken up in to categories:

Equipment (generally maintenance);
Software/licensing (e.g. subscription fees for purchased software); and
Other

Costs are also broken out by functionality groupings. These components, defined below, are:

1) Serialization
2) Local Data
3) Aggregation
4) Shared Data

Serialization and Traceability Questionnaire

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SERIALIZATION

For manufacturers and packagers, the SERIALIZATION component includes: (a) hardware, software and equipment needed to allocate serial numbers, encode them into a standard carrier technology and apply the carrier to individual drug packages on their packaging lines; (b) technology necessary at the line and site levels to allow drug packages to be uniquely identifiable throughout the supply chain.

For wholesalers and pharmacies the unit level serialization component includes hardware and software necessary to read serial numbers on drug packages during operations such as receiving, shipping, and picking or packing using automatic identification and data capture technologies. This would include both forward and reverse logistics processes.

The following questions request SERIALIZATION IMPLEMENTATION COSTS for the following categories: equipment and installation, engineering services, software, and other. RECURRING costs are requested for equipment, consummables (e.g. labels), software/licensing, and other. Inputting these itemized costs is preferred, but if they cannot be segregated, please input the TOTAL cost in the space provided.

Please input estimated costs in thousands of U.S. Dollars ($K) for implementation costs, or thousands of U.S. Dollars per year ($K/year) for recurring costs, for each category at the LINE, SITE, and/or ENTERPRISE level, as applicable. Enter a number or a range. (For example, enter "550" to indicate $550,000, or "60-70" to indicate a range of $60,000 to $70,000.) Where not applicable, please put 0 (zero).

35. Please input LINE level IMPLEMENTATION costs for SERIALIZATION in $K/line.

Equipment and installation	
Engineering services	
Software	
Other	
TOTAL	

36. Please input SITE level IMPLEMENTATION costs for SERIALIZATION in $K/site.

Equipment and installation	
Engineering services	
Software	
Other	
TOTAL	

37. Please input ENTERPRISE level IMPLEMENTATION costs for SERIALIZATION in $K.

Equipment and installation	
Engineering services	
Software	
Other	
TOTAL	

38. Please input LINE level RECURRING costs for SERIALIZATION in $K/line/year.

Equipment	
Software/licensing	
Consummables	
Other	
TOTAL	

39. Please input SITE level RECURRING costs for SERIALIZATION in $K/site/year.

Equipment	
Software/licensing	
Consummables	
Other	
TOTAL	

40. Please input ENTERPRISE level RECURRING costs for SERIALIZATION in $K/year.

Equipment	
Software/licensing	
Consummables	
Other	
TOTAL	

41. Have you combined costs across categories? Please let us know, and add any other comments.

Serialization and Traceability Questionnaire

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LOCAL DATA

This is typically a repository per packaging line or per site. For manufacturers and packagers, the Local Data component would: (a) supply line-level equipment with serial numbers and receive event data from them; (b) hold line-generated data about serial numbers and their associated packages; (c) communicate with and hold data generated by devices within the aggregation component; (d) communicate with the enterprise level shared data component.

For distributors and pharmacy chains, the Local Data component would, as appropriate: (a) communicate with serialization data readers such as bar code scanners; and (b) communicate with logistics systems to access information such as receipts, inventories, and shipments.

The following questions request LOCAL DATA IMPLEMENTATION COSTS for the following four categories: equipment and installation, engineering services, software, and other. RECURRING costs are requested for equipment (e.g. maintenance), software/licensing, and other. Inputting these itemized costs is preferred, but if they cannot be segregated, please input the TOTAL cost in the space provided.

Please input estimated costs in thousands of U.S. Dollars ($K) for implementation costs, or thousands of U.S. Dollars per year ($K/year) for recurring costs, for each category at the LINE, SITE, and/or ENTERPRISE level, as applicable. Enter a number or a range. (For example, enter "550" to indicate $550,000, or "60-70" to indicate a range of $60,000 to $70,000.) Where not applicable, please put 0 (zero).

42. Please input LINE level IMPLEMENTATION costs for LOCAL DATA in $K/line.

Equipment and installation	
Engineering services	
Software	
Other	
TOTAL	

43. Please input SITE level IMPLEMENTATION costs for LOCAL DATA in $K/site.

Equipment and installation	
Engineering services	
Software	
Other	
TOTAL	

44. Please input ENTERPRISE level IMPLEMENTATION costs for LOCAL DATA in $K.

Equipment and installation	
Engineering services	
Software	
Other	
TOTAL	

45. Please input LINE level RECURRING costs for LOCAL DATA in $K/line/year.

Equipment	
Software/licensing	
Other	
TOTAL	

46. Please input SITE level RECURRING costs for LOCAL DATA in $K/site/year.

Equipment	
Software/licensing	
Other	
TOTAL	

47. Please input ENTERPRISE level RECURRING costs for LOCAL DATA in $K/year.

Equipment	
Software/licensing	
Other	
TOTAL	

48. Have you combined costs across categories? Please let us know, and add any other comments.

Serialization and Traceability Questionnaire

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AGGREGATION

For the purposes of this work, the AGGREGATION component includes: (a) the hardware, software and equipment necessary to allocate and apply serial numbers to containers of multiple smaller packages; (b) associate the hierarchy of the serial numbers of the contained units with the outer container serial number; (c) line and site level technology that allows containers to be uniquely identifiable throughout the supply chain; and (d) anything needed to identify the container serial numbers, and to use their associated hierarchy to infer the units within the containers.

The following questions request AGGREGATION IMPLEMENTATION COSTS for the following four categories: equipment and installation, engineering services, software, and other. RECURRING costs are requested for equipment (e.g. maintenance), software/licensing, and other. Inputting these itemized costs is preferred, but if they cannot be segregated, please input the TOTAL cost in the space provided.

Please input estimated costs in thousands of U.S. Dollars ($K) for implementation costs, or thousands of U.S. Dollars per year ($K/year) for recurring costs, for each category at the LINE, SITE, and/or ENTERPRISE level, as applicable. Enter a number or a range. (For example, enter "550" to indicate $550,000, or "60-70" to indicate a range of $60,000 to $70,000.) Where not applicable, please put 0 (zero).

49. Please input LINE level IMPLEMENTATION costs for AGGREGATION in $K/line.

Equipment and installation	
Engineering services	
Software	
Other	
TOTAL	

50. Please input SITE level IMPLEMENTATION costs for AGGREGATION in $K/site.

Equipment and installation	
Engineering services	
Software	
Other	
TOTAL	

51. Please input ENTERPRISE level IMPLEMENTATION costs for AGGREGATION in $K.

Equipment and installation	
Engineering services	
Software	
Other	
TOTAL	

52. Please input LINE level RECURRING costs for AGGREGATION in $K/line/year.

Equipment	
Software/licensing	
Other	
TOTAL	

53. Please input SITE level RECURRING costs for AGGREGATION in $K/site/year.

Equipment	
Software/licensing	
Other	
TOTAL	

54. Please input ENTERPRISE level RECURRING costs for AGGREGATION in $K/year.

Equipment	
Software/licensing	
Other	
TOTAL	

55. Have you combined costs across categories? Please let us know, and add any other comments.

Serialization and Traceability Questionnaire

==========

SHARED DATA

The SHARED DATA component of a track and trace system consists of a long-term data repository such as a local or private cloud or semi-public cloud (shared) for holding serialized supply chain event data for an entire enterprise, and the ability to share those data with other enterprises as needed in an automated, secure and controlled manner. This includes the formatting and sharing of regulatory data including ePedigrees, pedigree checking reports and chain of custody/ownership reports, and non-regulatory data deliveries and/or access.

We recognize that there are multiple models for data sharing. We seek to differentiate between models that rely on a 3rd party data management service (mainly centralized or semi-centralized models, but could also include decentralized) versus models that rely on software solutions owned by the enterprise (mainly decentralized models). We recognize as well that some models may include both.

The following questions request SHARED DATA IMPLEMENTATION COSTS for the following categories: equipment and installation, engineering services, software, service set-up costs (assessed by a 3rd party data management service), and other. RECURRING costs are requested for equipment (e.g. maintenance), software/licensing, service fees (fee to use a third party's hosted system for data sharing), and other. Inputting these itemized costs is preferred, but if they cannot be segregated, please input the TOTAL cost in the space provided.

Please input estimated costs in thousands of U.S. Dollars ($K) for implementation costs, or thousands of U.S. Dollars per year ($K/year) for recurring costs, for each category at the LINE, SITE, and/or ENTERPRISE level, as applicable. Enter a number or a range. (For example, enter "550" to indicate $550,000, or "60-70" to indicate a range of $60,000 to $70,000.) Where not applicable, please put 0 (zero).

56. For the cost estimates you are able to share below, please indicate which of the following applies:

- ◯ Data sharing relies on software solutions owned by the enterprise
- ◯ Data sharing relies on a 3rd-party data management service
- ◯ Data sharing relies on both a 3rd-party data management service and software solutions owned by the enterprise

57. Please input LINE level IMPLEMENTATION costs for SHARED DATA in $K/line.

Equipment and installation	
Engineering services	
Software	
Service set up	
Other	
TOTAL	

58. Please input SITE level IMPLEMENTATION costs for SHARED DATA in $K/site.

Equipment and installation	
Engineering services	
Software	
Service set up	
Other	
TOTAL	

59. Please input ENTERPRISE level IMPLEMENTATION costs for SHARED DATA in $K.

Equipment and installation	
Engineering services	
Software	
Service set up	
Other	
TOTAL	

Serialization and Traceability Questionnaire

60. Please input LINE level RECURRING costs for SHARED DATA in $K/line/year.

Equipment	
Software/licensing	
Service fees	
Other	
TOTAL	

61. Please input SITE level RECURRING costs for SHARED DATA in $K/site/year.

Equipment	
Software/licensing	
Service fees	
Other	
TOTAL	

62. Please input ENTERPRISE level RECURRING costs for SHARED DATA in $K/year.

Equipment	
Software/licensing	
Service fees	
Other	
TOTAL	

63. Have you combined costs across categories? Please let us know, and add any other comments.

64. Is your cost information based on actual costs of an installed system, supplier information such as quotations (including internal suppliers such as IT departments), perceptions from other media, or other sources?

	Actual costs	Extrapolated from pilot programs	Calculated from a system design spec	Supplier information	Trade press	Perceptions	Other
Serialization	◯	◯	◯	◯	◯	◯	◯
Local Data	◯	◯	◯	◯	◯	◯	◯
Aggregation	◯	◯	◯	◯	◯	◯	◯
Shared Data	◯	◯	◯	◯	◯	◯	◯

Comments

Serialization and Traceability Questionnaire

65. Please estimate the below labor and additional costs associated with implementing or operating a serialization and traceability system to one or two significant digits, in units of thousands of U.S. Dollars ($K). Enter a number or a range. For example, enter "550" to indicate $550,000, or "60-70" to indicate a range of $60,000 to $70,000.

Incremental line-level operating costs (labor, $K/line/year)	
Incremental site-level operating costs (labor, $K/site/year)	
Incremental enterprise-level operating costs (labor, $K/year)	
Training	
Switching to a product identification standard such as GTIN (including new or upgraded supply chain master data management components)	
Changing business processes to accomodate serialization and traceability systems	
Validating the proper operation of incremental equipment	
Other labor to implement a system (Note: equipment installation labor is included in the "equipment" categories above.)	

66. If you inputted a cost for "Other labor to implement a system" in the previous question, please describe the major components.

Serialization and Traceability Questionnaire

67. For the following list of potential benefits first mentioned in Q.18, please indicate the system components necessary to achieve these benefits. If possible, please also indicate the estimated annual value -- either a number or a range -- of these benefits if realized, in thousands of U.S. Dollars per year ($K/year). Enter a number or a range. For example, enter "550" to indicate $550,000, or "60-70" to indicate a range of $60,000 to $70,000.

	Serialization alone	Serializaion + Local Data	Serialization + Local Data + Aggregation	Serialization + Local Data + Aggregation + Shared Data	Serialization + Local Data + Shared Data
Reduce costs and improve efficiencies related to recalls	◯	◯	◯	◯	◯
Value of benefit, in $K/year					
Improve inventory or materials management	◯	◯	◯	◯	◯
Value of benefit, in $K/year					
Improve procurement and invoicing automation	◯	◯	◯	◯	◯
Value of benefit, in $K/year					
Improve supply chain visibility	◯	◯	◯	◯	◯
Value of benefit, in $K/year					
Reduce costs related to chargebacks	◯	◯	◯	◯	◯
Value of benefit, in $K/year					
Reduce costs related to returns	◯	◯	◯	◯	◯
Value of benefit, in $K/year					

Serialization and Traceability Questionnaire

Please tell us a little about yourself.

68. Please provide us with some information about the main contributor to the questionnaire reponses. Choose the department and role that most closely matches your function.

	Individual contributor	Manager	Director	Vice President	President
Logistics	◯	◯	◯	◯	◯
Procurement	◯	◯	◯	◯	◯
Supply Chain	◯	◯	◯	◯	◯
Manufacturing	◯	◯	◯	◯	◯
Packaging	◯	◯	◯	◯	◯
Quality Assurance	◯	◯	◯	◯	◯
Regulatory Affairs	◯	◯	◯	◯	◯
Information Technology	◯	◯	◯	◯	◯
Corporate	◯	◯	◯	◯	◯
Finance	◯	◯	◯	◯	◯

Who else contributed to this questionnaire (department and role)?

69. How familiar are you with with the issue of serialization and traceability?

◯ I am a subject matter expert

◯ My expertise is in the technical aspects of serialization and traceability, and I defer to others regarding regulatory or company policy matters

◯ My expertise is in the regulatory and program management aspects of the issues, and I defer to others for technical matters

◯ I am somewhat familiar with the issues and with my organization's responses to them

◯ I am slightly familiar with the issues

Other (please specify)

Serialization and Traceability Questionnaire

70. May we contact you if we have additional questions? If so, please provide your contact information.

Name	
Title	
Organization	
Telephone	
E-mail address	
Address (line 1)	
Address (line 2)	
City, state and zip code	

71. Please feel free to add any additonal comments about this questionnaire or any of its subject matter.

Appendix B: Follow-Up Interview Guide

Appendix B: Follow-Up Interview Guide

Follow-Up Interview Guide for Questionnaire Respondents

Thanks for agreeing to a follow-up conversation with us about your high-level perceptions and assumptions.

General questions:

1. What barriers other than those described in the questionnaire do you think impede implementation of a national serialization and traceability system? For example, the questionnaire asks about internal barriers and challenges – such as integration with existing systems or the recurring cost of implementation – as well as external barriers such as lack of clear regulatory requirements or coordination with supply chain trading partners. Are there additional perceptions in your organization around the feasibility of implementing a national system? Are they primarily internal to your organization, or are they linked to your organization's external landscape?

2. Some respondents expressed concern over data security (illegal breaches such as hacks, and improper access to proprietary information) under a serialization and traceability system.

    a. What steps is your organization taking in this regard, and what assurances do you/would you demand of your trading partners?

    b. Are there solutions to the data security issue that you find particularly compelling?

3. What benefits other than those listed in the questionnaire do you think could result from a national serialization and traceability system? For example, the questionnaire asks about benefits associated with recall management or improvements to inventory management or improvements to supply chain visibility. What doesn't the questionnaire capture?

4. For the benefits you identified in the questionnaire, what incremental costs will there be to fully realize these benefits, beyond the cost to implement a serialization and traceability system?

5. Do you think one sector in the supply chain in particular benefits most from a national serialization and traceability system? Which one, and why?

6. Do you think other customers, clients or end-users such as patients and consumers will benefit from a national serialization and traceability system? Why?

7. How do you currently vet your supply chain partners (suppliers, customers, and contractors) for business process security and physical security (where lack of security would make the introduction of counterfeited, stolen, or diverted drugs easier)?

8. What additional vetting do you anticipate your organization doing in the absence of a national serialization and traceability system?

9. Do you see a role for payers such as insurance companies—or major government programs such as Medicare—in the national discussion on counterfeiting? What should that role look like?

10. What other comments do you have for us that were not captured in the questionnaire?

Questions specific to your response:

11. Where you have shared cost estimates that seem lower or higher than those shared by others in your sector, we would like explore what was or was not included in your estimate.

12. Where you have not been able to provide us with a cost estimate, we would like to explore why

13. We would like to explore any barriers or benefits you have particularly emphasized

14. We would like to explore any written comments you have made in your response

15. What's most useful for your organization to talk about the final report's conclusions—receiving a copy of the final report, attending a presentation, or both?

16. It's difficult to anticipate in advance of the final report's release, but do you anticipate this sort of cost analysis as helpful for your organization's thinking in the next two years?

Appendix C: Cost Spreadsheet Template for Vendor Interviews

Appendix C: Cost Spreadsheet Template for Vendor Interviews

Medium Manufacturer

FOR A BASIC SYSTEM

IMPLEMENTATION COSTS

					Cost ($000K)			
	Cost Category	Sub-step Description	One time / Ongoing	Units	Median	Min	Max	Comments
Serialization								
	Hardware & Software Cost	everything from system implementor such as control system & camera	One Time	Per Line				
		engineering services such as functional specs and factory acceptance	One Time	Per Line				
	Service Cost	system integration, validation, project management	One Time	Per Line				
Local Data								
	Hardware & Software Cost	Site serial number management	One time	Per Site				
	Hardware & Software Cost	Enterprise serial number management	One time	Per Enterprise				
	Service Cost	Site serial number management Engineering & Implementation	One time	Per Site				
	Service Cost	Enterprise serial number managemetn Engineering & Implementation	One time	Per Enterprise				
Aggregation								
	Hardware Cost	major equipment	One Time	Per line				
	Service Cost	engineering	One Time	Per Site				
	Service Cost	Implementation services, project management etc.	One Time	Per Site				
	Service Cost	training	One Time	Per Site				
Shared Data								
		Hardware	One Time					
		Software	One Time					
		Service setup fee	One Time					

ONGOING COSTS

		Sub-step Description	One time / Ongoing					Comments
Serialization								
a		major equipment maintenance	Ongoing					
c		Software maintenance	Ongoing					
Local Data								
a		hardware maintenance	Ongoing					
b		Software maintenance	Ongoing					
c		Data management costs	Ongoing					
Aggregation								
a		major equipment maintenance	Ongoing					
b		Software maintenance	Ongoing					
c								
Shared Data								
a		Hardware maintenance costs	Ongoing					
b		Software maintenance costs	Ongoing					
c		Data management costs	Ongoing					
d		Service fees	Ongoing					

Wholesaler

IMPLEMENTATION COSTS

	Cost Category	Sub-step Description	One time / Ongoing	Units	Cost ($000K) Median	Min	Max	Comments
Serialization								
a		Data Capture Equipment costs	One time					
b		Data Capture Computer hardware costs	One time					
c		Data Capture Software costs	One time					
d		system integration, project management	One time					
Local Data								
a		Computer hardware costs	One time					
b		Computer Software costs	One time					
c		system integration, project management	One time					
Aggregation								
a		Computer hardware costs	One time					
b		Computer Software costs	One time					
c		system integration, project management	One time					
d		training costs	One time					
Shared Data								
a		Computer hardware costs	One time					
b		Computer Software costs	One time					
c		system integration, project management	One time					
d		Service setup costs	One time					

ONGOING COSTS

	Cost Category	Sub-step Description	One time / Ongoing	Units	Cost ($000K) Median	Min	Max	Comments
Serialization								
a		major equipment maintenance	Ongoing					
b		misc equipment maintenance	Ongoing					
c		Software maintenance	Ongoing					
d								
Local Data								
a		hardware maintenance	Ongoing					
b		Software maintenance	Ongoing					
c		Data management costs	Ongoing					
Aggregation								
a		major equipment maintenance	Ongoing					
b		Software maintenance	Ongoing					
c								
Shared Data								
a		Hardware maintenance costs	Ongoing					
b		Software maintenance costs	Ongoing					
c		Data management costs	Ongoing					
d		Service fees	Ongoing					

Chain Pharmacy

IMPLEMENTATION COSTS

	Cost Category	Sub-step Description	One time / Ongoing	Units	Cost ($000K) Median	Min	Max	Comments
Serialization								
a		Data Capture Equipment costs	One time					
b		Data Capture Computer hardware costs	One time					
c		Data Capture Software costs	One time					
d		system integration, project management	One time					
Local Data								
a		Computer hardware costs	One time					
b		Computer Software costs	One time					
c		system integration, project management	One time					
Aggregation								
a		Computer hardware costs	One time					
b		Computer Software costs	One time					
c		system integration, project management	One time					
d		training costs	One time					
Shared Data								
a		Computer hardware costs	One time					
b		Computer Software costs	One time					
c		system integration, project management	One time					
d		Service setup costs	One time					
Communications Services								
a		Computer hardware costs	One time					
b		Computer Software costs	One time					
c		system integration, project management	One time					
d		Service setup costs	One time					

ONGOING COSTS

	Cost Category	Sub-step Description	One time / Ongoing	Units	Cost ($000K) Median	Min	Max	Comments
Serialization								
a		major equipment maintenance	Ongoing					
b		misc equipment maintenance	Ongoing					
c		Software maintenance	Ongoing					
d								
Local Data								
a		hardware maintenance	Ongoing					
b		Software maintenance	Ongoing					
c		Data management costs	Ongoing					
Aggregation								
a		major equipment maintenance	Ongoing					
b		Software maintenance	Ongoing					
c								
d								
Shared Data								
a		Hardware maintenance costs	Ongoing					
b		Software maintenance costs	Ongoing					
c		Data management costs	Ongoing					
d		Service fees	Ongoing					
Communications Services								
a		Hardware maintenance costs	Ongoing					
b		Software maintenance costs	Ongoing					
c		Service fees	Ongoing					

Independent Pharmacy

IMPLEMENTATION COSTS

	Cost Category	Sub-step Description	One time / Ongoing	Units	Cost ($000K) Median	Min	Max	Comments
Serialization								
a		Data Capture Equipment costs	One time					
b		Data Capture Computer hardware costs	One time					
c		Data Capture Software costs	One time					
d		system integration, project management	One time					
Local Data								
a		Computer hardware costs	One time					
b		Computer Software costs	One time					
c		system integration, project management	One time					
Aggregation								
a		Computer hardware costs	One time					
b		Computer Software costs	One time					
c		system integration, project management	One time					
d		training costs	One time					
Shared Data								
a		Computer hardware costs	One time					
b		Computer Software costs	One time					
c		system integration, project management	One time					
d		Service setup costs	One time					
Communications Services								
a		Computer hardware costs	One time					
b		Computer Software costs	One time					
c		system integration, project management	One time					
d		Service setup costs	One time					

ONGOING COSTS

	Cost Category	Sub-step Description	One time / Ongoing	Units	Cost ($000K) Median	Min	Max	Comments
Serialization								
a		major equipment maintenance	Ongoing					
b		misc equipment maintenance	Ongoing					
c		Software maintenance	Ongoing					
d								
Local Data								
a		hardware maintenance	Ongoing					
b		Software maintenance	Ongoing					
c		Data management costs	Ongoing					
Aggregation								
a		major equipment maintenance	Ongoing					
b		Software maintenance	Ongoing					
c								
d								
Shared Data								
a		Hardware maintenance costs	Ongoing					
b		Software maintenance costs	Ongoing					
c		Data management costs	Ongoing					
d		Service fees	Ongoing					
Communications Services								
a		Hardware maintenance costs	Ongoing					
b		Software maintenance costs	Ongoing					
c		Service fees	Ongoing					

Appendix D: Technology Increments

Appendix D: Technology Increments

The following sections explain the technology components examined in this report that comprise a pharmaceutical serialization and traceability system. These components can be structured in multiple ways to implement any number of technology models, including “centralized systems,” where data is stored in either one or a small number of centralized repositories, or “distributed models,” where data is stored in repositories maintained by supply chain participants or by third parties on their behalf.

The technology components for a unit-level serialization and traceability solution include:

- Unit-level serialization
- Local data
- Aggregation
- Shared data

Unit-Level Serialization

Today, with a few exceptions, pharmaceutical manufacturers identify products only at the Stock Keeping Unit (SKU) and lot level rather than uniquely identifying each individual unit of sale. To uniquely identify pharmaceutical product at the unit level, manufacturers and repackagers (which remove finished drugs from the manufacturer’s original package and repackage them in a different size and/or type of package under license) would need to add the application of unique serial numbers to their existing packaging operations. Wholesalers and pharmacies would need to be able to capture the serial numbers on unit-level drug packages using automatic identification and data capture (AIDC) technologies.

For pharmaceutical manufacturers and repackagers this component would include the hardware, software, and equipment needed to allocate serial numbers, encode them into a standard carrier technology such as a barcode, and apply the carrier to individual drug packages on their packaging lines. It would include any technology necessary at the line level and site level to allow drug packages to be uniquely identifiable throughout the supply chain.

This report assumes that serial numbers for use in the U.S. supply chain must follow the FDA’s Serialized Numeric Identifier (SNI) guidance. The anticipated standard carrier technology at the unit package level is a 2D barcode. Some companies may choose to include Radio Frequency Identification (RFID) tags as a second carrier technology on each package, but the study’s cost assessment does not assume this option.

Unit-level serialization for wholesalers and pharmacies would include the hardware and software necessary to read the serial number on drug packages during receiving, shipping, picking or packing, and during inventory management operations using AIDC technology. This would include "reads” within forward and reverse logistics processes.

Local Data

An important component in a serialization and traceability system is a place to record the relationships between the serial numbers that are assigned or captured and the business processes that the serialized drug packages go through. This technology component is referred to as “local data” because it will typically be a local repository per packaging line or per site for performance reasons. Local data would include IT hardware and software.

For manufacturers and repackagers this component would include line- and/or site-level controllers necessary to:

- Receive and hold blocks of available serial numbers prior to allocation and association with physical drug packages;
- Communicate with the unit-level serialization packaging line level equipment, supplying it with serial number allocations and receiving confirming commissioning events from it;
- Hold production event data generated by the unit-level serialization packaging line level equipment about the association of allocated serial numbers and the packages that they were attached to;
- Communicate with devices within the aggregation component and hold the containment hierarchies they produce; and
- Communicate with the enterprise-level shared data component.

For wholesalers and chain pharmacies this component would include site-level systems necessary to:

- Communicate with the unit-level serialization data capture devices and existing inventory management systems;

- Generate and hold production event data related to serial number-based warehouse activities including receiving, shipping, picking or packing, and inventory management operations;
- Communicate with devices within the aggregation component and hold the containment hierarchies produced by them; and
- Communicate with the enterprise-level shared data component.

For independent pharmacies this component will likely not need to exist because these organizations will probably make use of a data management solution through either a solution provider or their wholesale drug suppliers.

Aggregation

Not all trading partners handle pharmaceutical products at the same level. Manufacturers package individual drug packages into cases, which are then placed on pallets and shipped to wholesalers and pharmacies. In some scenarios, wholesalers do not open the manufacturer's cases to reveal the unit-level drug packages. In those instances drugs are received, stored, and shipped at the case level. In other scenarios, however, wholesalers place individual units into mixed containers known as totes along with other drugs. To allow trading partners to share information about the individual units within a case, tote, or pallet, manufacturers and wholesalers must capture these parent-child relationships as the product is packed. This is known as aggregation. Aggregation also requires that higher-level containers bear serial numbers.

For pharmaceutical manufacturers, repackagers, and wholesalers, the elements of the aggregation component would include the hardware, software, and equipment necessary to allocate case- and pallet-level serial numbers, encode them into a standard carrier technology, apply the carrier to the containers, and associate the full hierarchy of the serial numbers contained within the case or pallet with the outer container serial number.

For all supply chain participants except independent pharmacies, aggregation would include the software and/or services necessary to identify the container serial numbers, their associated containment hierarchy, and the use of that hierarchy to infer the units within the containers. This process is known as inference.

The use of inference by parties within the supply chain is a powerful tool for increasing the efficiency of serialization-based "track and trace" systems. When handling pallets and cases, manufacturers and repackagers could employ inference to identify the unit-level serial numbers being shipped to their customers from their distribution centers. Wholesalers and chain pharmacies could use it when receiving pallets and cases from upstream trading partners, and wholesalers would be able to use it when shipping cases sealed by the original manufacturer. Without the use of inference, all of these scenarios would require the organization to open every case and read the unit-level serial numbers on every unit to know exactly which drug packages are present.

Shared Data

To capture the transaction history of a drug as it moves through distribution, supply chain partners will need the capacity to share product location and transaction information. The shared data component of a serialization and traceability system consists of a long-term data repository for holding serialized supply chain event data for an entire enterprise. It also includes the ability to share this data with other enterprises as needed in an automated, secure, and controlled manner. Data repositories could be maintained by each organization (a "distributed" model), or one or several repositories could be shared by supply chain stakeholders (a "central" or "semi-central" model).

The elements that comprise the shared data component are highly dependent on the system being implemented. Distributed data models would likely require investments in hardware and software, or service fees for a hosted enterprise solution. Central and semi-central data models would require ongoing service fees to third-party service providers. Cost estimates presented in Sections 4 and 5 do not show differentiated costs for these models.

Sharing data would require each supply chain member to make use of secure data communications software or services to send the data to their trading partners, whether directly or through a third party. Many pharmaceutical manufacturers, wholesalers, and chain pharmacies already make use of this type of software or service for data transmission, known as Electronic Data Interchange (EDI). For a full serialization and traceability system, however, the volume of data would increase substantially above that of today's needs.

This report assumes that independent pharmacies would make use of third-party services for the data sharing component, which would require an Internet connection. Additionally, the report's cost analysis assumes that pharmacies will make use of a handheld 2D barcode scanner.

Appendix E: Manufacturer Labor Costs

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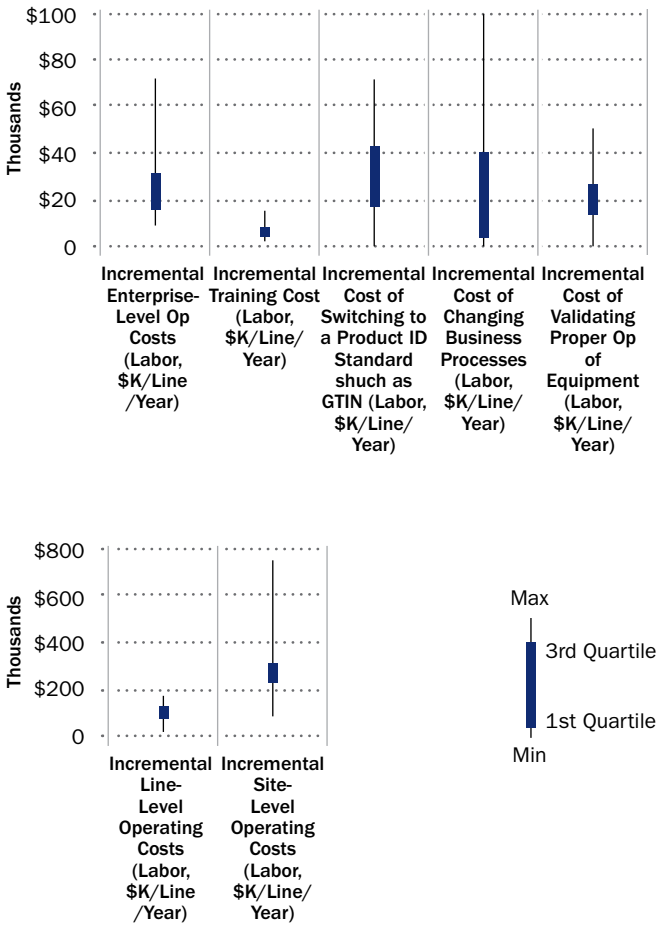
Some manufacturers were able to break out their anticipated labor related costs for a serialization and traceability system. To normalize the enterprise-level costs for the manufacturers, this report has divided these costs by each respondent's number of packaging lines.

Manufacturer Cost Estimates—Incremental Labor Costs per Packaging Line or per Site



Appendix F: Glossary

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1D (one-dimensional) barcode: A barcode that uses a single physical dimension, such as a linear barcode. Example:

2D (two-dimensional) barcode: A barcode that uses two physical dimensions, such as a data matrix barcode. Example:

Aggregation: Data that records exactly which packages are in the next largest package via serial numbers.

Authentication: Confirmation that a serial number found on a given unit is a legitimate serial number produced by the manufacturer or repackager.

Case: A shipping container that holds multiple drug units or bundles of drug units.

Chargeback: A charge from a wholesaler to a manufacturer to compensate the wholesaler when it must sell product below the purchase price, typically to accommodate a manufacturer's contract arrangements with the end-buyer (such as a hospital or pharmacy).

Counterfeiting: Deliberate imitation of a product or product packaging.

Diversion: The illicit movement of product out of its legitimate distribution channel.

DPMS: Stands for Drug Pedigree Messaging Standard; a document-based GS1 standard that assists the pharmaceutical supply chain with creating an interoperable system to trace drugs in a way that can comply with existing document-based pedigree laws.

Drug unit: The smallest saleable package of a drug.

Enterprise: The organization as a whole; used when referring to costs allocated at this level, as opposed to costs allocated more granularly, such as for each site within an organization.

EPCIS: Stands for Electronic Product Code Information Services; a general-purpose GS1 standard designed to enable serial number-related data capture and sharing within and across enterprises in supply chains.

ERP: Stands for Enterprise Resource Planning; a software system used to manage many aspects of one's business.

GTIN: Stands for Global Trade Identification Number; a GS1 standard for identifying product class.

Inference: Knowing which serial numbers are contained within a larger container by reading the larger container's serial number and using aggregation data supplied by the upstream trading partner.

Packaging line: A physical assembly line used to place drugs into packaging and shipping containers.

Pallet: A large shipping container holding multiple cases.

Rebate: A retroactive refund or credit; pharmaceutical manufacturers generally pay rebates for covered outpatient drugs reimbursed under state Medicaid programs.

RFID: Stands for Radio Frequency Identification; technology using electronic tags and readers to pass data through radio waves.

Serialization: Assigning a unique identifier (serial number) to a saleable package or logistical unit.

Tote: A container typically used to transport a mix of units or small packages; often the primary container shipped from a wholesaler to a dispenser (such as a hospital or pharmacy).

Traceability: The ability to determine and document a package's distribution history throughout a supply chain.

Unit level: Refers to individual instances of the smallest saleable unit of a drug.

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Dr. Yun Kang is also a partner at AutoID Consulting, and formerly led research initiatives at MIT's Auto-ID Lab.

Mr. Paul Schmidt is currently a senior manager in the IT organization at a large U.S. retailer. Prior to his current role he spent 20 years working on supply chain issues for a leading consulting firm.

Additionally, Mr. Dirk Rodgers provided consulting work. Mr. Rodgers owns Dirk Rodgers Consulting, LLC, and is the founder and author of the online publication RxTrace. He previously worked as senior consultant for Cardinal Health, a large healthcare wholesaler.

End Notes

End Notes

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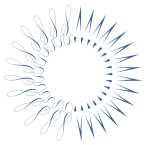

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