Benefits and Impact of the DSCSA on Supply Chain Adjacent Areas

In collaboration with

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Introduction

The HDA Research Foundation partnered with Rutgers Business School to have graduate students work on real-world pharmaceutical business problems. For the fall 2019 semester, a team of students worked to understand the benefits and impacts of the Drug Supply Chain Security Act (DSCSA) on supply chain adjacent activities. A supply chain adjacent activity can be understood as an activity that is indirectly linked to the pharmaceutical supply chain. For example, functional areas such as human resources, legal and information technology (IT) would be considered supply chain adjacent.

As part of the collaboration between the Foundation and the Rutgers team, a panel of industry experts was assembled to guide, consult and provide feedback during the semester's project. The panel was instrumental in assisting the Rutgers team on understanding the industry's views on DSCSA, developing a survey and analyzing the results. The survey was used to capture industry members' perspectives on DSCSA legislation by role in the supply chain, i.e., manufacturer, distributor or dispenser.

The pharmaceutical industry has already completed a great deal of work to meet the requirements of DSCSA. While meeting legislative requirements, the industry finds itself with more data than ever before. This influx of data brings new opportunities and challenges to the industry. This white paper will begin to explore how the pharmaceutical industry has reacted to, plans to react to, and adapts to the changing dynamics of the DSCSA.

Project Background

DSCSA is designed to promote greater safety in the pharmaceutical industry by requiring serialization and an interoperable system to easily verify, track, and trace drugs through the supply chain. The Food and Drug Administration (FDA) is responsible for the implementation of the law and outlined a ten-year timeline for completion. The majority of the work to date has been on implementing processes and information technology infrastructure in the manufacturing and repackaging spaces, while deadlines for wholesale distributors and dispensers are quickly approaching. The focus of DSCSA is creating a more safe and secure supply chain with data that the industry has not previously worked with. The focus of this project was to learn how different organizations in the industry are planning on using this data. Will it only be to meet the regulatory requirements or will the economics of the industry change? What kinds of benefits or impacts do companies anticipate?

Below are the requirements as outlined by the DSCSA:

1. **Product identification:** Manufacturers and repackagers are required to put a unique product identifier on certain prescription drug packages. For example, using a barcode that can be easily read electronically.

2. **Product tracing:** Manufacturers, wholesale drug distributors, repackagers and dispensers (primarily pharmacies) in the pharmaceutical supply chain are required to provide information about a product and who handled it each time it is sold in the U.S. market.

3. **Product verification:** Manufacturers, wholesale drug distributors, repackagers and dispensers (primarily pharmacies) are required to establish systems and processes to verify the product identifier on certain prescription drug packages.

4. **Detection and response:** Manufacturers, wholesale drug distributors, repackagers and dispensers (primarily pharmacies) are required to quarantine and promptly investigate a drug that has been identified as suspect, meaning that it may be counterfeit, unapproved, or potentially dangerous.

5. **Notification:** Manufacturers, wholesale drug distributors, repackagers and dispensers (primarily pharmacies) are required to establish systems and processes to notify FDA and other stakeholders if an illegitimate product is found.

6. **Wholesaler licensing:** Wholesale distributors are required to report their licensing status and contact information to the FDA. This information will then be made available in a public database.

7. **Third-party logistics provider licensing:** Third-party logistics providers, those who provide storage and logistical operations related to distribution, are required to obtain a state or federal license.

Methodology

This project is qualitative in nature. DSCSA is still new and is yet to be fully defined, so the full quantitative aspects of DSCSA are not apparent. With the expertise of HDA and the advisory panel, a survey was developed, distributed and analyzed in weekly meetings. As part of the survey development, the state of the industry was discussed. This was crucial in defining the problem statement and the project plan. The information collected through submissions was anonymous and confidential.

Survey Structure

The goal of the survey was to understand how the industry is preparing to meet the requirements of DSCSA while positioning itself to leverage the serialized data that will be available as a result. Using SurveyGizmo, a link to a questionnaire consisting of eight questions with multiple sections was distributed on October 30th and closed on December 4th, 2019. At the close of the survey there were 58 total responses: 35 manufacturers, 18 distributors, and five dispensers.

The first questions focused on categorizing the role and size of each respondent. The next set of questions aimed to capture how the organization is preparing or prepared to collect and use serialized information, whether it be only to meet legislative requirements or be ready to analyze information right away. The bulk of the survey was questions relating to benefits and impacts in key areas. These areas were defined through collaboration and designed to spark some conversation and thought in areas that may not have obvious benefits or impacts. Finally, the survey asked if there were any current benefits with the partial implementation of DSCSA and what barriers exist that may be blocking benefits. Most questions provided an area for open-ended responses.

Panel Discussions

The implementation of DSCSA is complex, causing many organizations to change the way they do business. The initial discussions with the panel provided insights to help the Rutgers group understand who the key players are, what the expectations of implementation and post-integration are, and how each organization is positioning themselves to optimize available resources.

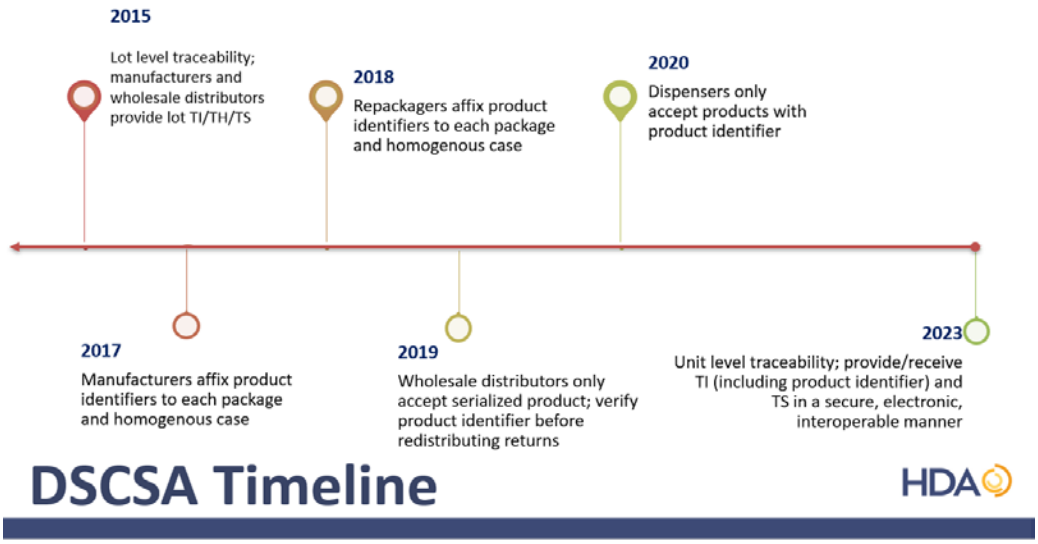
This knowledge provided a solid baseline to ask more impactful survey questions. During the weekly discussions new iterations of the survey were presented to the panel. With their feedback the survey questions were better defined.

Once the survey was complete, the Rutgers group, HDA, and the advisory committee began high-level analysis of the data. These meetings showed the impact of the survey's approach and if clarifying questions were required.

Current Situation

DSCSA has deadlines for key milestones of implementation dating back to 2013. The goal of the act is to build an electronic, interoperable system that will identify and trace certain prescription drugs as they are distributed in the United States. The final deadline is expected to be in November of 2023, when there will be unit-level traceability. Given the complexity of implementation FDA has allowed an enforcement discretion period on several milestones. Some other countries that also are implementing serialization of pharmaceuticals have been more prescriptive in their laws to define the "system," such as the EU, where serial numbers will be verified through a central database. On the other hand, the legislation and guidelines set by the FDA are laid out in a way that puts much of the onus on the industry to develop interoperability. While this creates additional work, the focus of DSCSA is on the results rather than the vehicle that allows each organization to optimize their solutions.

DSCSA Timeline of Implementation



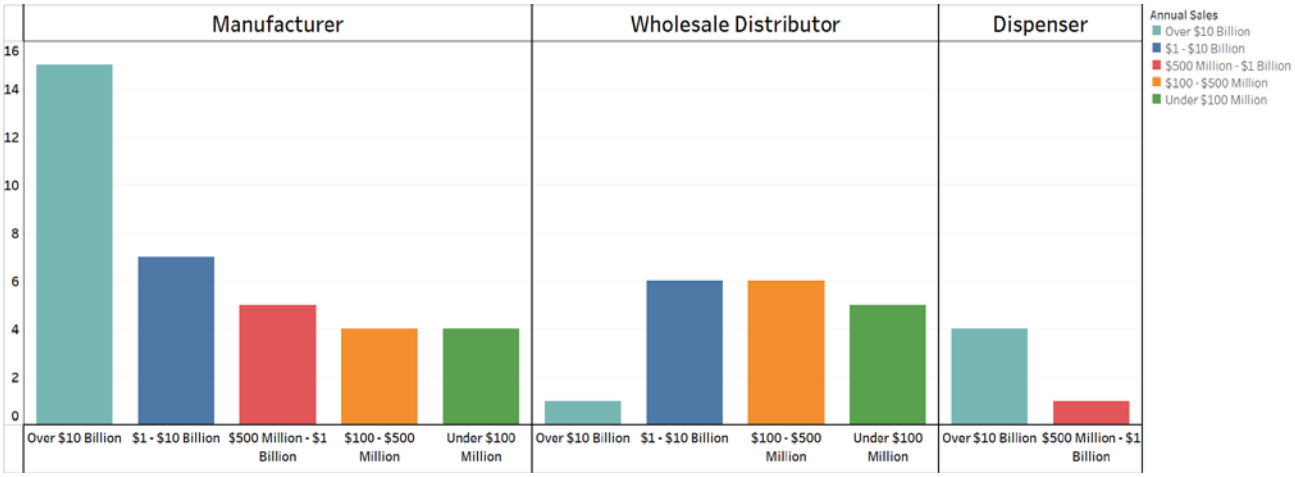
It is clear through discussion and analysis that there are differing views on the benefits and impacts of the legislation. Given the complexity and significant resource requirements of implementation, organizations have been focused on meeting the requirements by the deadlines. Organizations have only started to explore the opportunities beyond meeting the requirements. DSCSA only requires end-to-end visibility upstream in particular circumstances. It does not require full data visibility downstream beyond an immediate trading partner due to protections around commercially sensitive data, potentially limiting the opportunities of serialized data.

There are expected benefits associated with the implementation of DSCSA. Different service providers are advertising their ability to help organizations leverage the newly required data. Depending on the organization there seems to be a view of incremental benefit. Data are already available to analyze many situations, but serialized data may provide greater depth to the analysis. There are already some members of the supply chain that are working through the impacts and realizing benefits in areas such as IT, warehousing and logistics.

Survey Results

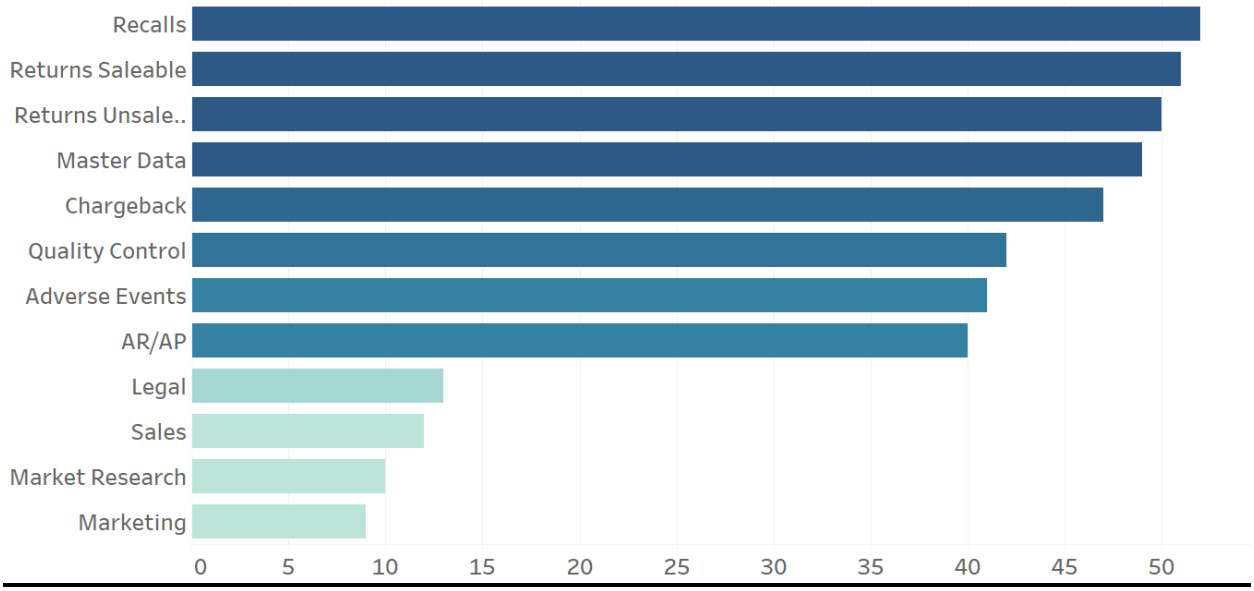
Survey Response Profile

The survey response profile was made up of manufacturers, wholesale distributors, and dispensers. These roles were separated into five categories related to revenue. In total, the 58 respondents were comprised of 35 manufacturers, 18 distributors and five dispensers. In terms of revenue 34% fell into the over $10 billion range, 22% were between $1 and $10 billion, 10% were $500 million - $1 billion, 17% $100 - $500 million and 16% fell into the under $100 million category. There is a relatively good mix of viewpoints represented in the survey. Most representation is from larger manufacturers while the least is from dispensers.



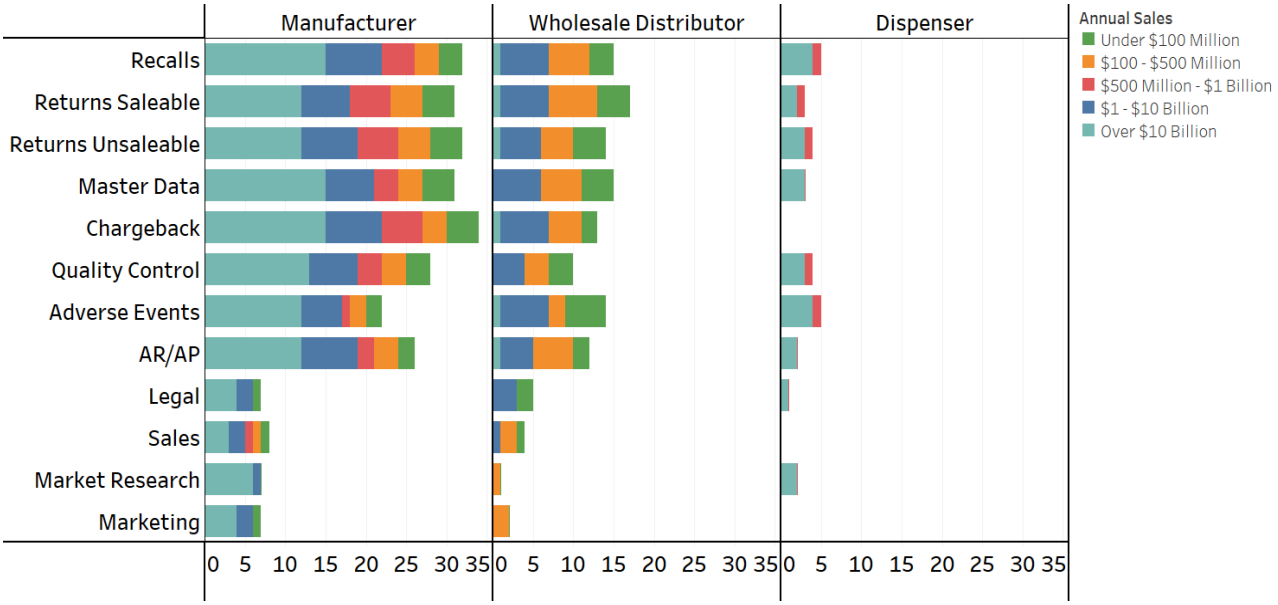
Benefits

Below is a chart with an aggregated view of where the industry anticipates benefits once DSCSA is implemented and serialized data are available. The area of recalls received the strongest response, with 52 or 90% of respondents selecting this area. The lowest level of response is in the area of marketing, with only 16% of respondents. The data show that as the area of benefit moves further away from a supply chain operational oriented area there are fewer respondents that anticipate a benefit.



Category	Number of Responses	Anticipated Benefits Percentage Out of 58 Respondents
Recalls	52	90%
Returns Saleable	51	88%
Returns Unsaleable	50	86%
Master Data	49	84%
Chargebacks	47	81%
Quality Control	42	72%
Adverse Events	41	71%
AR/AP	40	69%
Legal	13	22%
Sales	12	21%
Market Research	10	17%
Marketing	9	16%

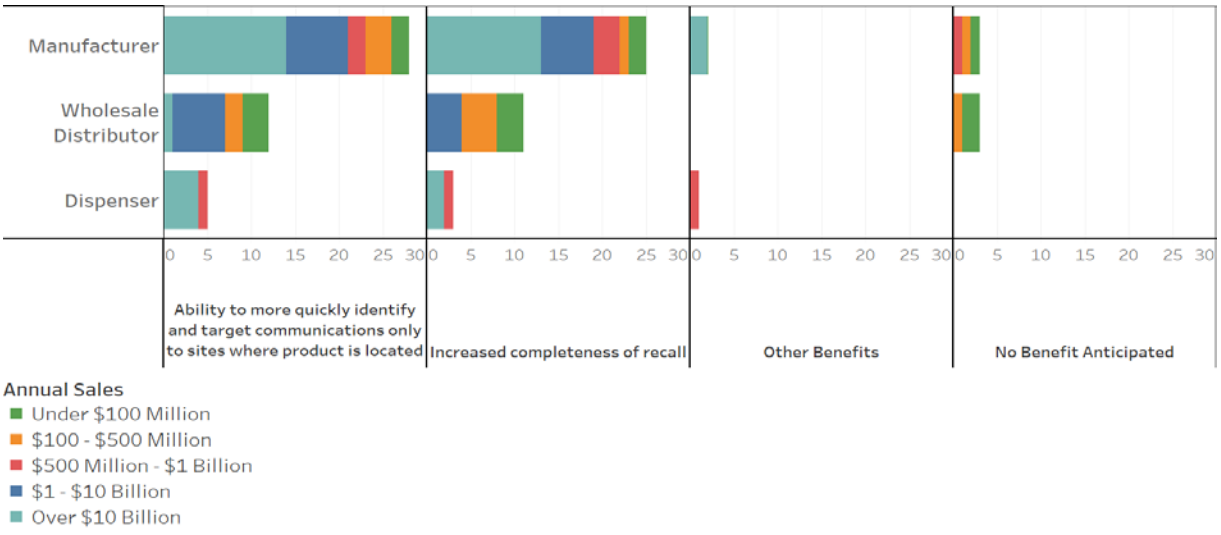
When the data are broken up into smaller categories there is a similar pattern in response. When the data are split by company roles and revenue, the data show that manufacturers, distributors and dispensers have differing perspectives on which functional areas could see a benefit. In the area of chargebacks manufacturers have a strong response of 97% and distributors have a lower rate of 72%. Dispensers responded with no benefit anticipated in this area. Quality control is another area with a discrepancy. Manufacturers and dispensers both responded with 80%, while distributors only replied with 56%.



Category	Manufacturer		Wholesale Distributor		Dispensers	
	Responses	Percentage Out of 35	Responses	Percentage Out of 18	Responses	Percentage Out of 5
Recalls	32	91%	15	83%	5	100%
Returns Saleable	31	89%	17	94%	3	60%
Returns Unsaleable	32	91%	14	78%	4	80%
Master Data	31	89%	15	83%	3	60%
Chargebacks	34	97%	13	72%	0	0%
Quality Control	28	80%	10	56%	4	80%
Adverse Events	22	63%	14	78%	5	100%
AR/AP	26	74%	12	67%	2	40%
Legal	7	20%	5	28%	1	20%
Sales	8	23%	4	22%	0	0%
Market Research	7	20%	1	6%	2	40%
Marketing	7	20%	2	11%	0	0%

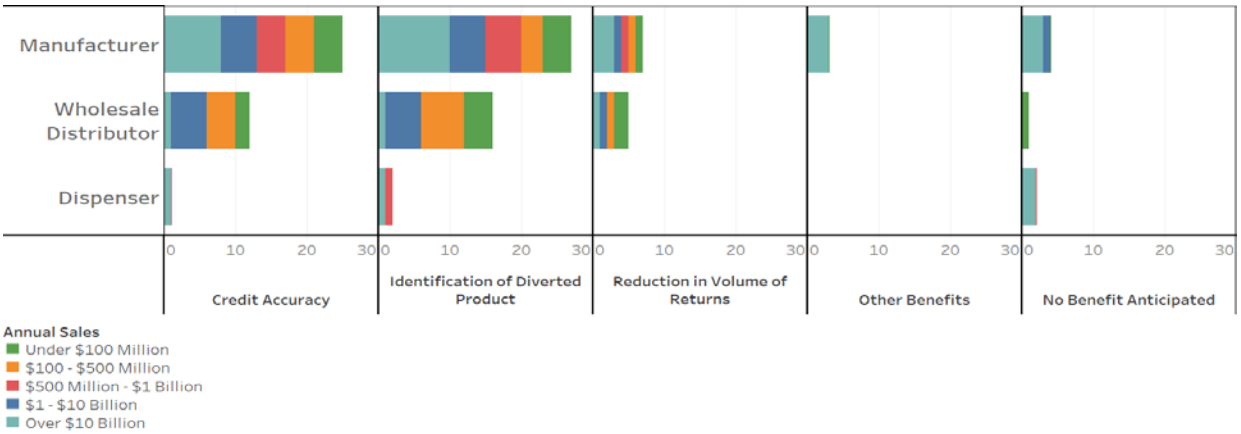
Recalls

With the use of serialized data, the industry could see increased effectiveness of recalls through targeted communication and an increased level of recall completeness. With recalls being more effective the industry reduces the risk of leaving recalled products out in the market. At the same time a product that is not part of the recall will not be unnecessarily pulled. The recall process can be more deliberate in engaging the right downstream partners. Serialized data could be leveraged to send automatic status updates to customers when a recall is necessary. This higher level of efficiency and accuracy could reduce the overall response time for recalls.



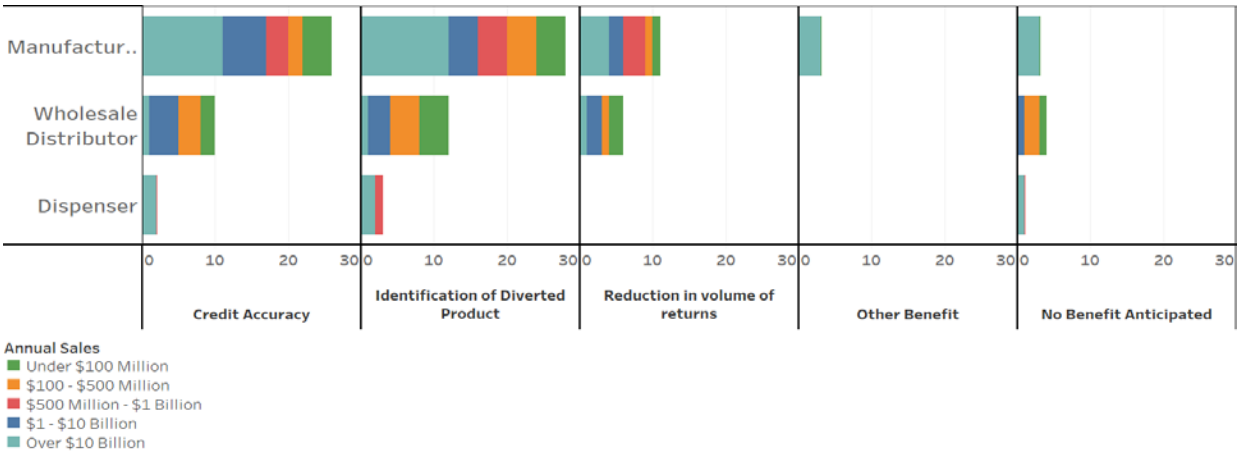
Saleable Returns

In the area of saleable returns, there is a potential benefit for manufacturers and distributors, specifically in the areas of credit accuracy and identification of a diverted product. The overall volume of returns is not anticipated to decrease but the reconciliation associated with the returns process would be more accurate. Today, when a product is returned by the customer, it is difficult to track the item back to the original purchase order. Since DSCSA will require each unit to be tracked the data can be used to understand what is truly coming through reverse distribution. This could potentially increase the accuracy of credits issued as well as aid in the identification and reduction of counterfeit products in the pharmaceutical supply chain.



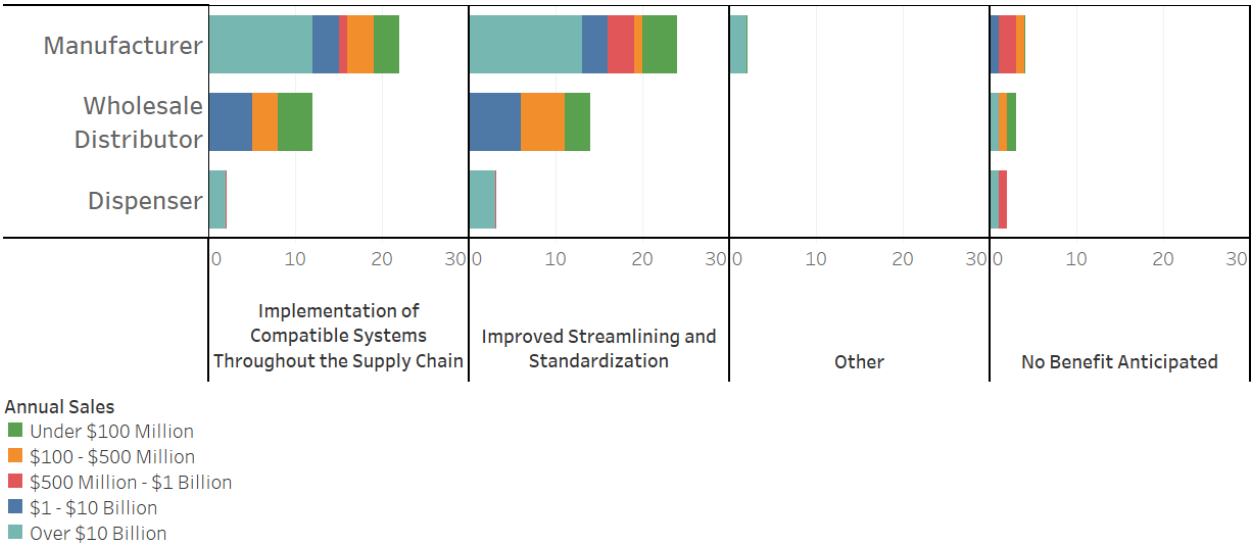
Unsaleable Returns

The area of unsaleable returns follows a similar pattern to saleable returns though more distributors responded that there is no benefit anticipated. Looking at the returns functional area holistically the main benefit of serialized data would be increased credit accuracy and the identification and reduction of suspect, fraudulent or diverted product.



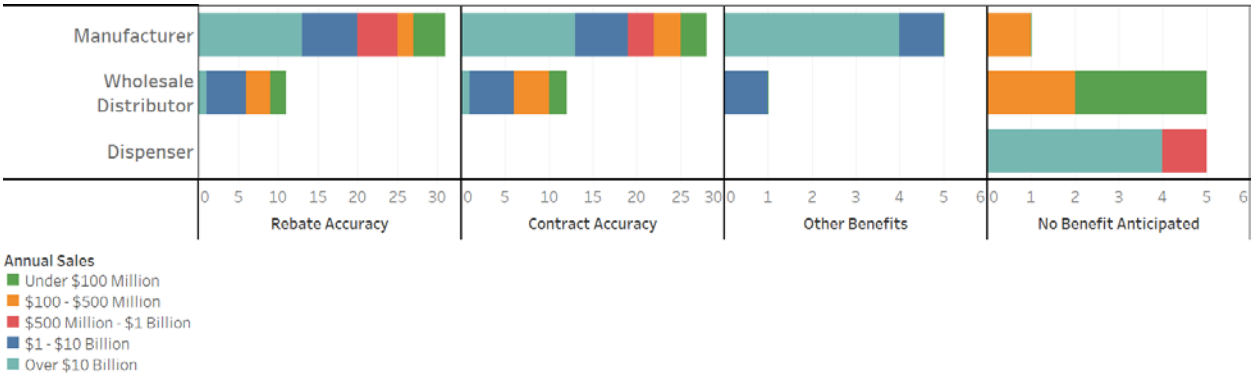
Master Data

Since DSCSA was enacted there have been new data challenges requiring efforts from an IT, warehousing and logistics perspective. There is an overall positive response that master data will benefit from DSCSA, but there are differing viewpoints on approach. As part of most implementation or integration projects data cleanup is required. This provides an opportunity to assess existing data to ensure that systems are utilizing good information. The challenge across the industry, is that different organizations are either implementing or researching different systems. For instance, some organizations are gravitating toward working with the Global Data Synchronization Network (GDSN). Others are using more manual processes like spreadsheets. Organizations are evaluating the benefit, expense and complexity of more and less sophisticated approaches to master data and whether industry will navigate to one system in the future is unclear.



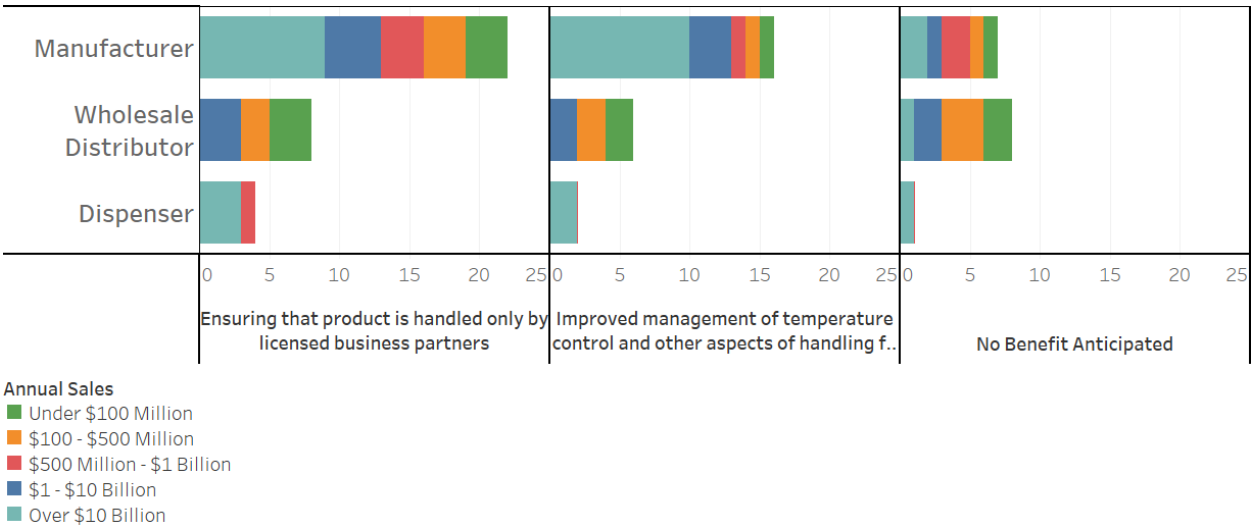
Chargebacks

Manufacturers and distributors strongly anticipate the benefits in the area of chargebacks, especially in terms of rebate and contract accuracy. The benefits would mostly aid in increasing adherence to contracts rather than the drafting of documents. Respondents also wrote that DSCSA could increase credit accuracy by being able to trace product back to the purchase order and issuing rebate credits at the original purchase price. Dispensers do not anticipate any benefit in this area.



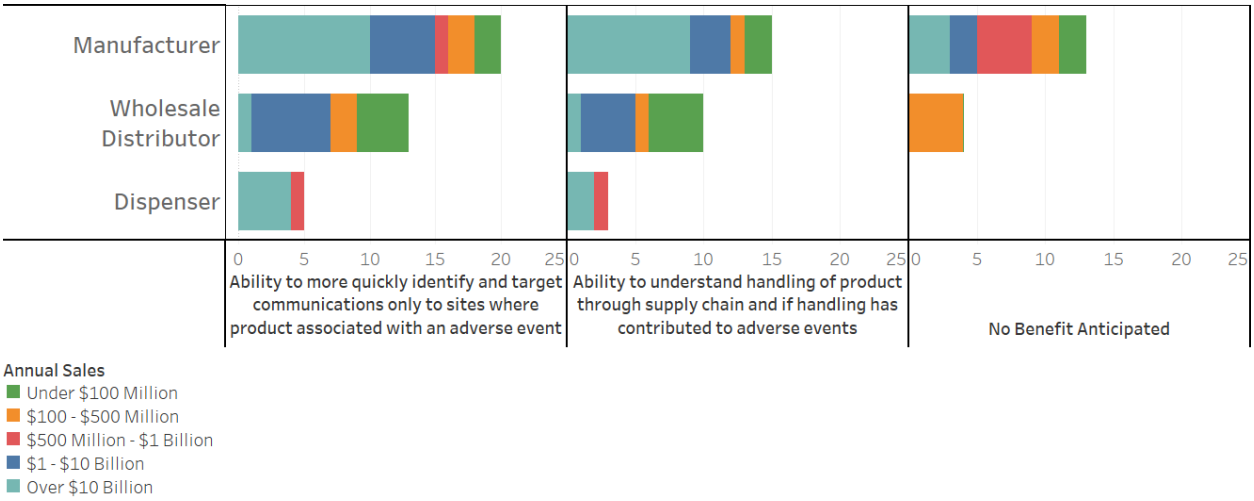
Quality Control

Many of the manufacturers, distributors and dispensers anticipate a positive benefit in the area of quality control when it comes to ensuring that product is being handled by licensed business partners and handled properly. About one-third of respondents answered that there would not be a benefit. As an industry that is already highly regulated the benefits of serialized data could be incremental instead of being a catalyst for a major change.



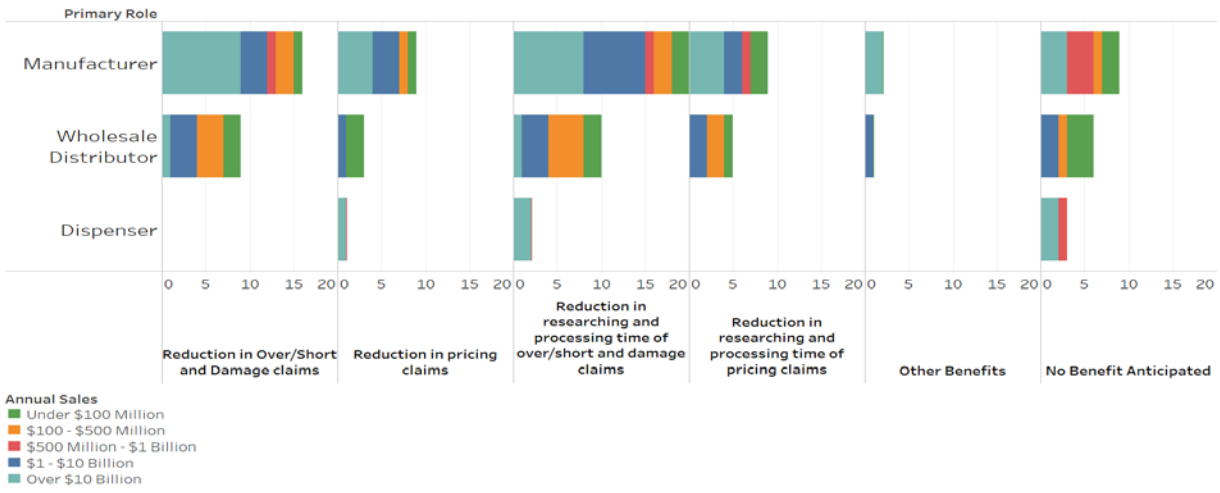
Adverse Events

Most respondents do anticipate a benefit in this area, but about 37% of manufacturers do not anticipate a benefit. Like recalls, serialized data can help with targeted communication and reducing overall response time. The data could aid in identifying the root cause by tracking the serialized product back through the supply chain to see where it could have been mishandled.



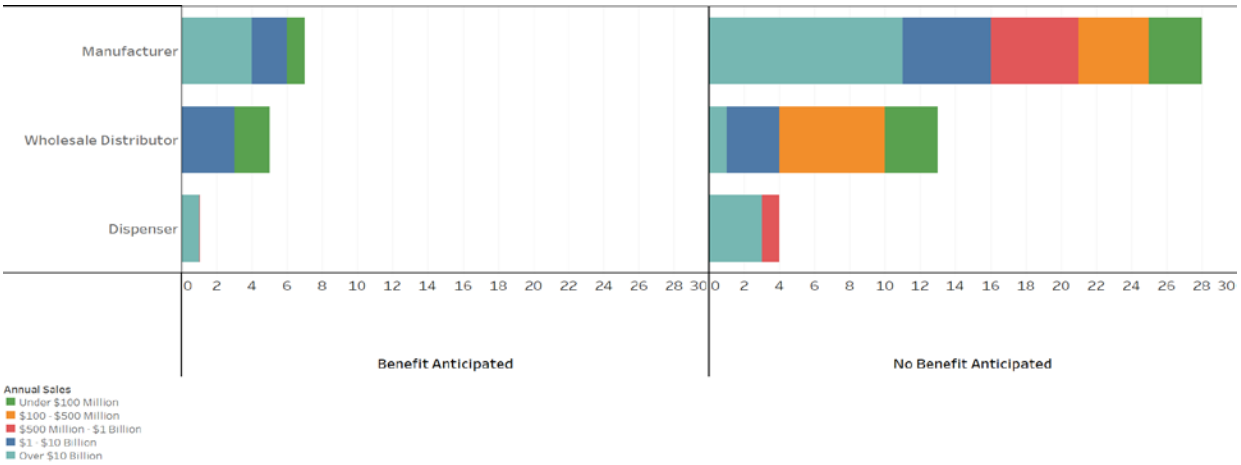
Accounts Receivable/Payable

The benefits in this area are not expected to be seen right away. Some of the open-ended responses indicated that including the serialized data in price discrepancy issues could create a negative impact in the near term. The benefits would not be realized until the root cause analysis was completed, and adjustments are made to the process to prevent similar issues from reoccurring in the future.



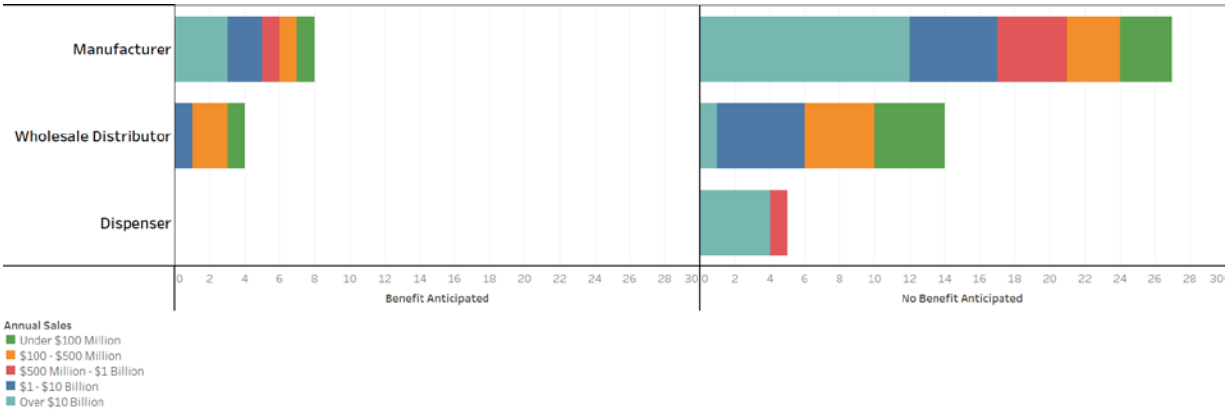
Legal

Most respondents did not anticipate a benefit related to legal processes. However, legal teams are expected to be involved in many of the supply chain operational areas. One respondent wrote that because operationally legal teams review and support the business, they have gained a strong understanding of DSCSA. At the same time a strong network has been developed with outside legal representatives. This could aid in issues being resolved quickly. Other legal benefits would be associated with the fact that there will be a product identifier that could identify illicit players and protect those acting lawfully within the industry.



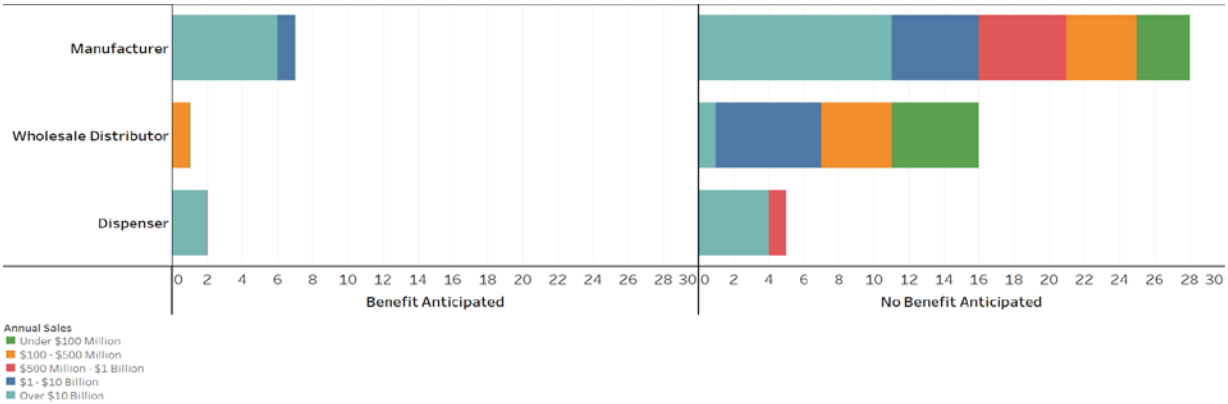
Sales

According to the respondents this area is expected to have incremental benefits rather than a profound change. The survey did not have a strong quantitative response in this area, but the written responses provided some perspective. Successfully meeting the requirements of DSCSA could provide a strong message to customers. It could be a competitive advantage that shows a company's control over its supply chain. In the long term this could be less of an advantage as the industry collectively implements DSCSA. The survey does show that organizations of different sizes and roles are at different levels of implementation. One respondent suggested mobile use of the data. There could be apps that use the serialized barcode to show product information.



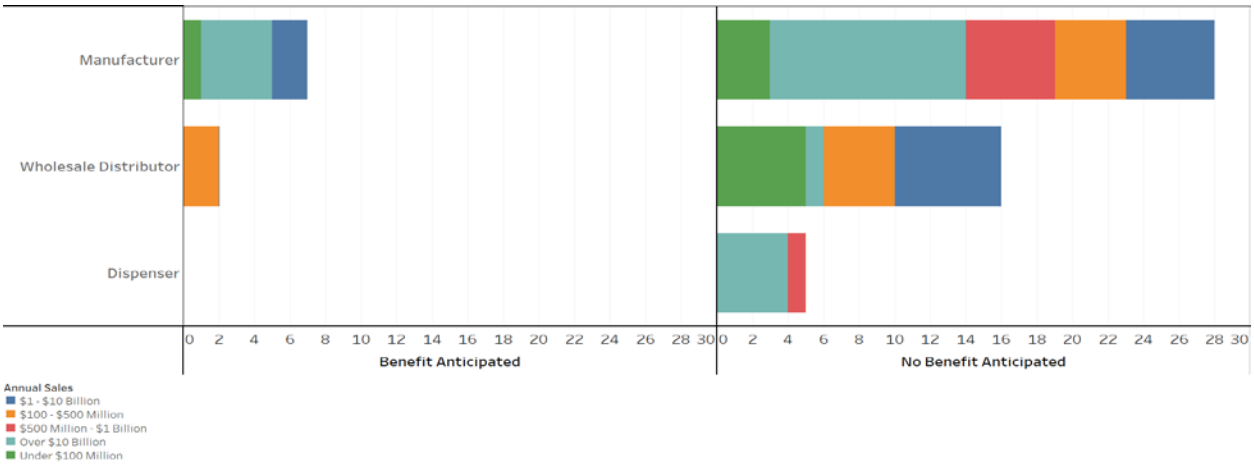
Market Research

Most respondents did not feel this is an area of benefit. Those who selected this area of having a benefit felt there could be stronger market analytics, have a better understanding of where the product is being used and overall visibility of product movement. There are already many tools and applications to aid in market research though serialized data that could be useful and powerful to leverage



Marketing

Marketing received a similar response as market research in terms of the number of respondents that identified it as an area of benefit. The serialized data would be other elements in an area that already has a lot of information. The expected benefit would echo what was seen in sales and market research. The data could provide geographical data on where the product is used and be a competitive advantage by implementing DSCSA when others had not.



Impact

DSCSA is expected to have a profound impact on the pharmaceutical industry. Out of 58 respondents, more than 70% anticipated that acquisition and divestitures, trade agreements, internal staffing, and internal training would be affected. This trend is relatively consistent across the pharmaceutical supply chain, with little variation between manufacturers, wholesale distributors and dispensers. The number of industry members that will likely be impacted by DSCSA will increase in the future due to the implementation timeline and approaching milestones.

There is a readily visible connection between these areas and the implications caused by DSCSA and serialization. The industry can expect to see impacts in other areas not covered in this research paper. It should be noted that while the previous section only included benefits this section consists of impacts that may have either positive or negative depending on the individual company and its surrounding circumstances.

Trade Agreements

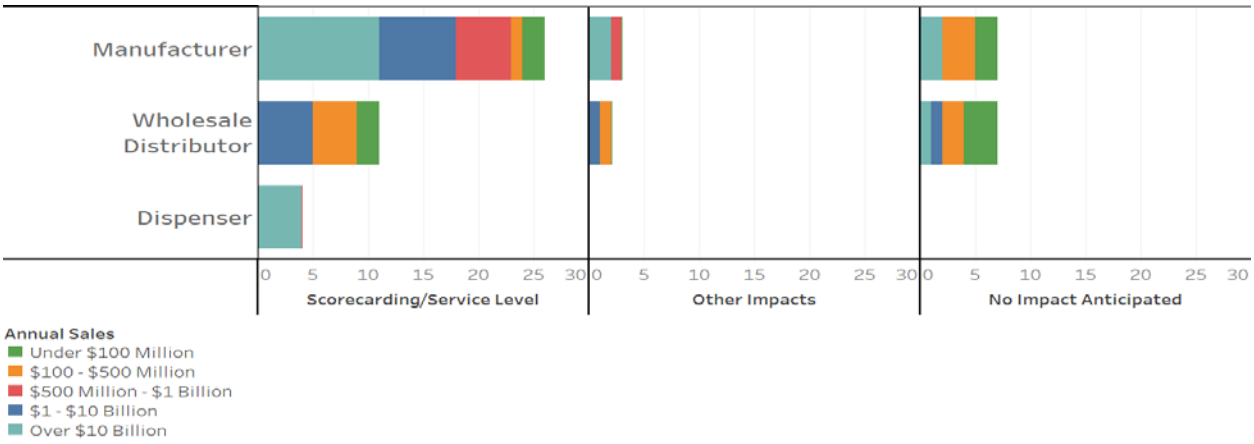
Approximately 74% of manufacturers reported anticipating an impact to their service level control processes or scorecarding methodology due to the DSCSA. Some individual responses made by manufacturers:

a. “Modifying contracts for partners to start sending data back.”
b. “Penalties for non-compliance to standards.”

Survey responses suggest that trade agreements and contracts will be affected by DSCSA and its mandates. Companies should consult their legal departments in making sure that their trade agreements properly reflect the requirements set forth by DSCSA.

Sixty-one percent of distributors report anticipating an impact on their service level control processes or scorecarding methodology. A plausible explanation for less impact on the distributor versus manufacturer is the DSCSA implementation timeline; distributors have not been exposed to the provisional requirements for as long as the manufacturers and hence may see less of an impact as of today. In the future, the distributors may see more of an impact in this category.

Additionally, it should be noted that serialization can have a positive impact on the industry’s trade agreements in the future. This is due to the processes related to tracking service level key performance indicators (KPIs) and scorecards becoming more efficient and visible. This may then lead to positive outcomes such as a reduction in penalties and improved service levels as well as potentially improving the customer-vendor relationship.

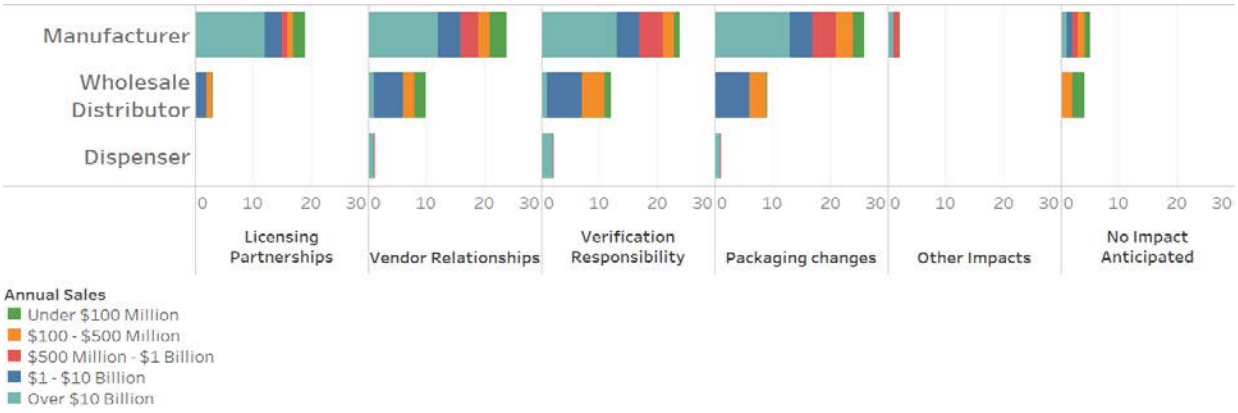


Acquisitions and Divestitures

Most manufacturer and distributor respondents reported an impact on processes associated with acquisitions and divestitures. Such processes include licensing partnerships, vendor relationships, verification responsibility and packaging changes.

One noteworthy survey comment was made by a manufacturer: “Serialization will add a new layer of complexity to M&A. This includes things such as transaction records and suspect investigations.” This statement alludes to the additional complexity of which party will be ultimately responsible for serialization and its impact within the combined entity.

DSCSA may complicate matters when it comes to acquisitions and divestitures. Serialization will add a layer of complexity as to which party is responsible for verification, how the packaging for products will change to conform to standards across both organizations, which IT systems will be used and how they will be integrated to handle the serialization needs of both organizations, and how the organizational structure change will impact the licensors and licensees of the organization(s).



Internal Staffing and Training Needs

Manufacturers and distributors report an anticipated need for additional staff due to the DSCSA, approximately 55%. The additional staffing needs are slightly more prevalent amongst the distributors and much more prevalent in larger organizations with higher reported revenue versus smaller organizations. This is likely because the volume of the additional activity generated by DSCSA is greater in the larger organizations which will require hiring additional employees.

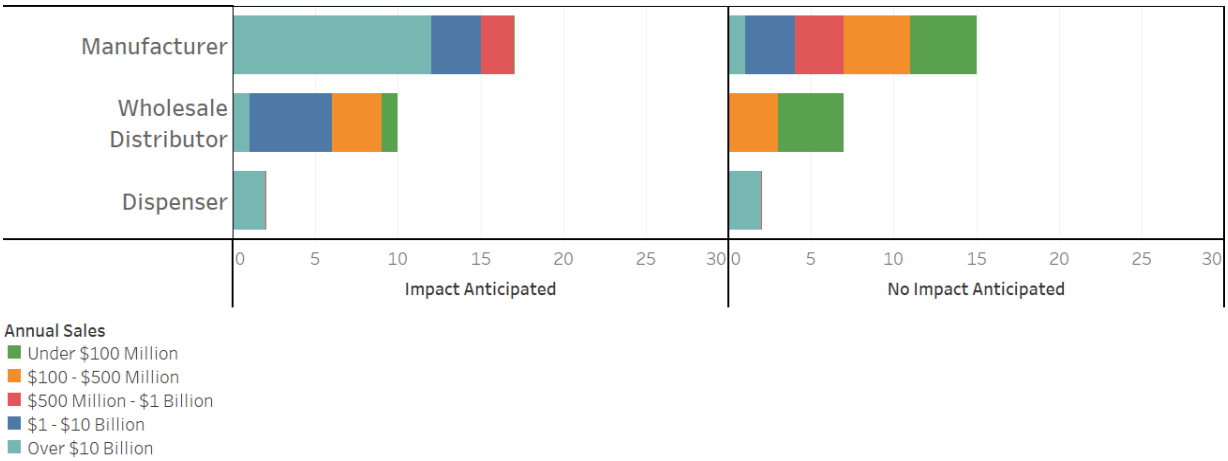
Additionally, manufacturers reported that they will require:

a. “Staff to support data analytics.”
b. “Staff with specialized expertise in the DSCSA mandates.”
c. “System upgrades concerning distribution, quality, and customer service that will be needed to accommodate the DSCSA (This will require additional trained personnel.)”

Wholesale distributors made the following noteworthy comments:

a. “The need for more staff will increase expenses”
b. “The need for increased staffing in frontline operations due to DSCSA, such as warehousing and picking.”
c. “Serialization will require more specialized staff across the industry to handle the increased workload, at least initially.”

Going hand in hand with an increase in the number of employees is the need to retrain existing ones. Both manufacturers and distributors are overwhelmingly anticipating the need to retrain and provide education to current employees. Distributors may experience a more operational impact on staffing needs and training requirements; indeed, many report the need to retrain warehouse, receiving and picking workers. Manufacturers reported an increased need for support staff on DSCSA expertise and data analytics — more so than a frontline operational need. No matter where the stakeholder is positioned in the pharmaceutical supply chain, it will be necessary for them to prepare their workforce for DSCSA.



Other Survey Questions

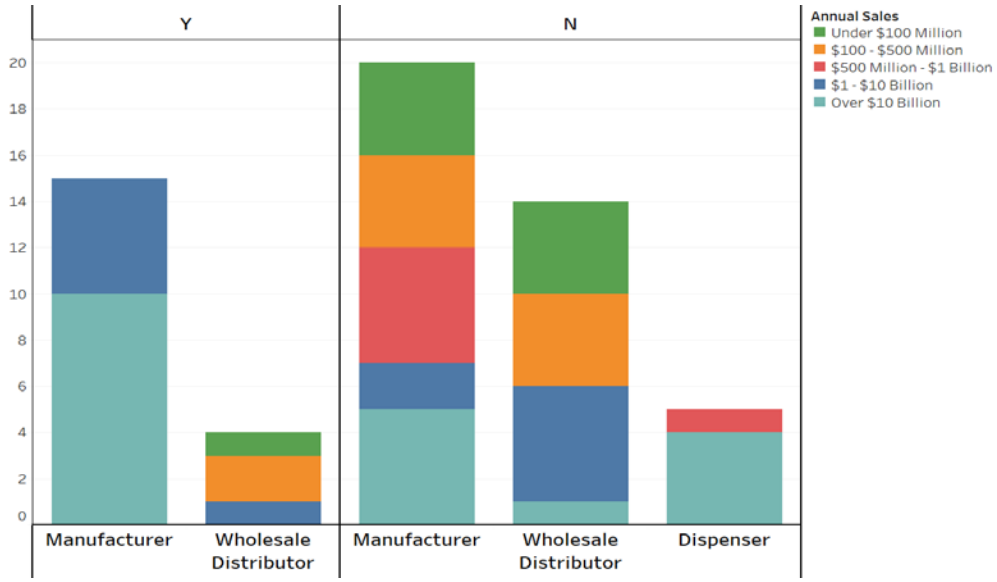
The industry is approximately seven years into the implementation of the requirements laid out by DSCSA. Quite a bit of work has already been completed with manufacturers being the furthest along in the implementation process and the deadline for distributors being imminent. Beyond the potential impacts and benefits, survey participants were asked if they have started to realize some benefits from the components of DSCSA that have been already implemented.

Given some of the potential benefits identified above, the survey also included questions on whether industry members are currently planning on leveraging serialized data and the other potential process benefits for commercial use and other value-added activities. Survey takers were asked if they currently have plans to build capabilities to analyze serialized data, since building these capabilities is a critical component in being able to use these data in the future. Lastly, survey participants were asked about the major barriers to realizing some of the benefits mentioned above.

Benefits from Implemented DSCSA

A little under half of the responding manufacturers reported that they have begun to realize benefits from those components of DSCSA that have been implemented. However, it is important to note that to date the group of respondents currently realizing benefits is limited to manufacturers with over $1billion in annual sales and a few wholesalers with a range of annual sales.

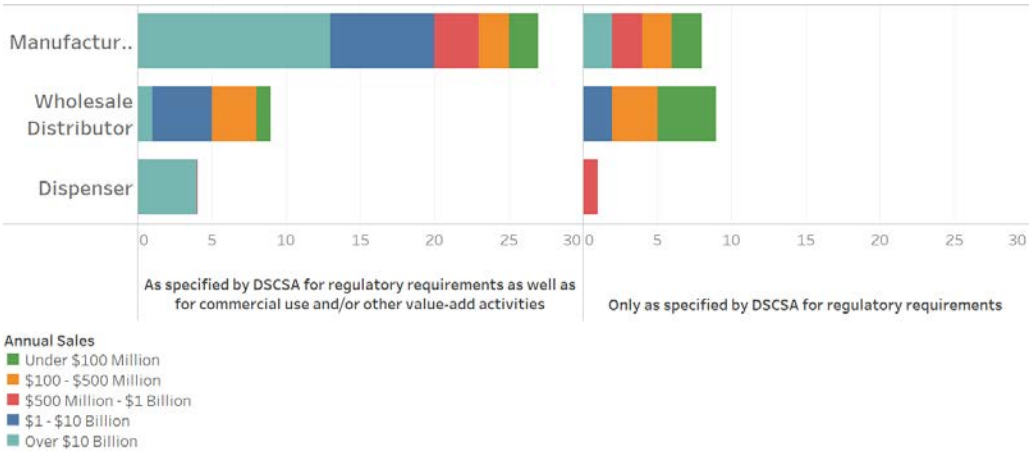
The benefits reported mostly fell into supply chain traceability, while there were a few that also reported that they have begun to realize benefits in reverse distribution and standardization. Examples of benefits specified as a result of traceability by manufacturers included: increased visibility to shipping/receiving exceptions and proof of delivery, improved cycle count accuracy and increased order accuracy for those distribution centers scanning outbound serialized products. Identification of suspect product was reported by a manufacturer as “easier.” While one distributor reported that they could identify whether the manufacturer sent a specific lot within the area of returns including returns reconciliation, the accuracy of the associated credit and the ability to see the volume of returns by each wholesaler.



Planned Use of Serialized Data

The majority of manufacturers and dispensers that responded to the survey indicated that they have plans to leverage serialized data to create value beyond the minimum requirements laid out by DSCSA. Distributors, on the other hand, were split with 50% responding that they planned on using the data only as required while the other half are planning to use the data for commercial use and other value-added activities. Across the board, it seems that the larger companies leaned more heavily towards using the data beyond the minimum requirements.

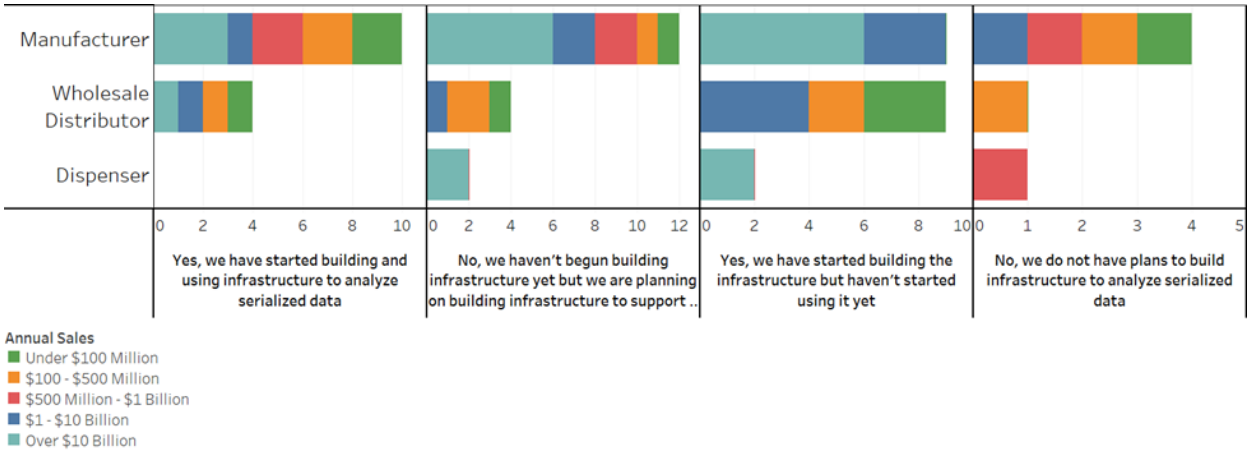
With the distributor enforcement deadline approaching, they are focused on meeting the minimum requirements at this time. Given the current reported trends across the groups we would expect that as they get further along in the implementation timeline the trend towards using data beyond what is required will continue to grow.



Plans to Build Serialized Data Analytics Infrastructure

A critical step in being able to analyze and utilize serialized data is planning and building infrastructure to support these capabilities. Since serialized data are new to organizations, the current thinking is that additional investment in education/training, staffing and capital may be necessary to fully capture, store, and analyze data and explore any potential opportunities. Even when an organization plans on only meeting the requirements of DSCSA, there will need to be a process put in place to collect and store all the information.

Roughly 90% of those that responded to the survey indicated they have plans to be able to analyze serialized data and are in differing stages of building and utilizing those capabilities. the industry seems to be in differing stages of building infrastructure with only a handful of smaller companies not planning on building infrastructure to analyze serialized data.

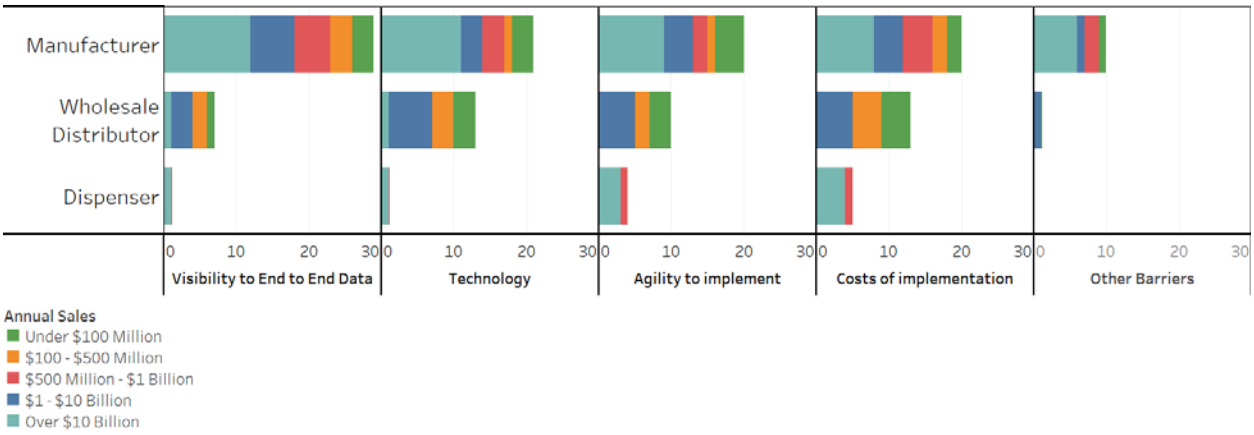


Major Barriers to Realizing Value

While there have been potential benefits identified there is still a long way to go. Respondents were asked what the major barriers are to realize the benefits. The survey focused on the areas of visibility to end-to-end data, technology, agility to implement, cost of implementation and offered the option of an “other” category where respondents could specify anything not mentioned.

All respondents are anticipating some barriers to realizing value. The barrier most selected by each group varied, with 72% of distributors selecting both cost and technology. All dispensers selected cost. A majority, 83%, of manufacturers selected visibility to end-to-end data. The requirements for DSCSA as they are currently laid out would mean that manufacturers would expect to have minimal end to end serialized data. They will have to collaborate with their business partners across the industry to gain greater visibility.

Those that selected “other” reported barriers mostly in the areas of governance, resources, challenges with technological implementations, and alignment and collaboration. Examples of governance included a need for standards and regulations for data sharing among trading partners. While in the area of technological implementation, one manufacturer reported having a concern around being able to achieve true interoperability when different technologies are being implemented.



Conclusion and Recommendations

This report has touched on some of the impacts and potential benefits to supply adjacent areas that are anticipated as the industry look towards 2023. The majority of those surveyed have reported interest in leveraging serialized data beyond the requirements to create additional value and most have plans to build capabilities to analyze serialized data. As the industry races toward 2023, the primary focus is making sure the requirements are met by the deadlines that have been set forth in the law. With this focus on compliance, it might be a bit too early to tell where all the impacts and benefits lie and what it will take to minimize the impacts and realize the benefits.

As the industry moves through the implementation of new technologies and processes, the Rutgers team recommends taking some of these ideas into account. First, the socialization of these changes to cross-functional partners. It may spark additional ideas on how to create value beyond the original intent of the legislation. As well as a follow-up survey post-2023 after all requirements have been met and the industry shifts their focus to minimizing impacts and exploring opportunities.

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