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Welcome

Perry Fri
Executive Vice President, Industry Relations, Membership & Education, HDA; and Chief Operating Officer, HDA Research Foundation
Before we get started...

• Today’s webinar is being recorded.
• All participant lines are muted.
• Presentation and audio-reply will be made available by Friday, December 20.

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Rutgers MBA & HDA Research Foundation
Benefits and Impacts of the DSCSA in Supply Chain Adjacent Areas

Presented by:
Farrah Agha, Lukas Soltysik, Arthur Bellis, Amy Tang
Rutgers University Team

Professor Anthony Taitt
Amy Tang - MBA, Marketing
Lukas Soltysik - MBA, Supply Chain Management; Finance
Arthur Bellis - MBA, Supply Chain Management; Finance
Farrah Agha - MBA, Supply Chain Management; Strategy & Leadership

HDA and HDA Research Foundation

Perry Fri, EVP Industry Relations, Membership and Education at HDA; COO at HDA Research Foundation
Justine Freisleben, VP Industry Relations at HDA
Rachel Sullivan, Project Manager at HDA Research Foundation

HDA Panel Members

Ameer Ali – AmerisourceBergen Corporation, Senior Manager, Manufacturer Operations
Jay Garvey – Boehringer-Ingelheim Pharmaceuticals Inc., Senior National Account Director
Dr. Asma Ishak-Mahdi – Walmart Pharmacy, DSCSA Serialization Lead
Mark Mcgee – Boehringer-Ingelheim Pharmaceuticals Inc., Executive Director US Supply and 3PM North America
Michelle Osmian – Teva Pharmaceuticals, Senior Director, Commercial Operations
Dianne Pfahl – Cardinal Health, Vice President, Strategic Sourcing National Brands
Endrit Vangjeli – GlaxoSmithKline, North America Supply Chain Partner - Tech
Background

- Legislation enacted by Congress on November 27, 2013 which requires an electronic, interoperable system to track and trace certain prescription drugs to be completed by November 27, 2023
- The law is intended to improve serialization, tracing and verification making it easier to recognize, trace & remove counterfeit & unsafe drugs from the market

*FDA has granted one year of enforcement discretion, until November 27, 2020, for the requirement that wholesale distributors verify product identifiers before reselling a return.

Problem Statement
What are some of the Impacts & Benefits of implementing DSCSA on supply chain adjacent functions and processes.

Approach
Survey & Panel Discussions with members of the industry currently in the process of implementing solutions to meet DSCSA requirements.
Survey Background

**Purpose:** To understand the current industry perspective and readiness of complying with the DSCSA requirements and how the industry plans to leverage serialized data within processes outside of Supply Chain.

**Format:** Surveygizmo questionnaire with open ended response opportunities

**Date(s):** 10/30/19 - 12/04/19

**Response:** 58 Total - 35 Manufacturers, 18 Distributors, and 5 Dispensers

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Survey Response Profile

[Bar chart showing the sales revenue distribution among manufacturers, wholesale distributors, and dispensers.]

- **Manufacturers:**
  - Over $10 Billion: 8
  - $1 - $10 Billion: 7
  - $500 Million - $1 Billion: 5
  - $100 - $500 Million: 4
  - Under $100 Million: 4

- **Wholesale Distributors:**
  - Over $10 Billion: 4
  - $1 - $10 Billion: 5
  - $100 - $500 Million: 4
  - Under $100 Million: 4

- **Dispensers:**
  - Over $10 Billion: 1
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Recall

Key Takeaway:
- Serialized Data can streamline communication & logistics in bringing product back

Returns-Saleable

Key Takeaway:
- Potential to be able trace a returned item back to the invoice and price it that it was originally sold resulting in possible
  - Increased credit accuracy
  - Proper Identification of Returns
Key Takeaway:
- Similar benefit to saleable returns

Key Takeaway:
- Data clean up during implementation aids efficiency
- Standardization may occur internally or with strategic partners, but is not anticipated initially industry wide
Chargebacks

**Key Takeaway:**
- Serialized data can aid in adherence to contracts
- Potential to be able trace a returned item back to the invoice and price it that it was originally sold resulting in possible increased rebate credit accuracy & ability to reconcile item sold and rebate issued

Quality Control

**Key Takeaway:**
- Benefits are incremental due to the industry being already highly regulated
**Adverse Events**

<table>
<thead>
<tr>
<th></th>
<th>Manufacturer</th>
<th>Wholesale Distributor</th>
<th>Dispenser</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ability to more quickly identify and target communications only to sites where product associated with an adverse event</td>
<td><img src="image1" alt="Graph" /></td>
<td><img src="image2" alt="Graph" /></td>
<td><img src="image3" alt="Graph" /></td>
</tr>
<tr>
<td>Ability to understand handling of product through supply chain and if handling has contributed to adverse events</td>
<td><img src="image4" alt="Graph" /></td>
<td><img src="image5" alt="Graph" /></td>
<td><img src="image6" alt="Graph" /></td>
</tr>
</tbody>
</table>

**Key Takeaway:**
- Root cause analysis can be implemented with better information and communication through serialized data

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**DSCSA Impact - Supply Chain Adjacent Areas**

**Key Takeaway**
- The pharmaceutical industry as a whole can expect to be impacted in these areas
- More than 70% of industry stakeholders will be impacted in A&D, Trade Agreements, and Internal Staffing
- Approximately half of the industry stakeholders anticipate the need to train their workforce, due to the DSCSA*
- Impacts are both negative & positive

*Internal training will likely be more prevalent in the future state.
**Acquisitions & Divestitures**

Key Takeaway

- "Serialization will add a new layer of complexity to M&A. This includes things such as transaction records and suspect investigations", anonymous manufacturer

- Serialization will add a layer of complexity to strategic management:
  - 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 will they be integrated?
  - How will the DSCSA impact the licensors and licensees of the organization as well as the underlying license?

**Trade Agreements**

Key Takeaway

- Both manufacturers and distributors report an impact on service evaluation processes, including KPI measurement and scorecarding
- Such processes may become more efficient across the industry, resulting in:
  - Reduction in penalties
  - Improved service levels
  - Improvement in customer-vendor relationships
### Staffing

#### Key Takeaway
- Slightly more than half of industry respondents report a need for more staff members. This is likely to increase in the future.
- Staffing needs are more prevalent in larger organizations, likely due to the larger volume of workload generated by serialization.
- Manufacturers and distributors have divergent needs for employee skill-sets.

### Training/Education

#### Key Takeaway
- Distributors anticipate a greater need to provide education for operational roles:
  - Warehousing, receiving, picking
  - Enabling functions will also be impacted to a degree.
- Manufacturers anticipate a greater need to provide education for strategic roles:
  - Data analytics
  - DSCSA mandate expertise
  - IT professionals.
Other Survey Questions

Realization of Benefits - Today

Key Notes
- 43% of Manufacturers that responded to the survey reported that they have begun to realize benefits from the components of DSCSA that have been implemented.
- 23% of Wholesale Distributors that responded are reporting that they have also begun to realize benefits.
- 0% of Dispensers that responded are reporting realization of benefits. Many are earlier in their implementation process as their deadlines are the last in the implementation timeline.
Planned Use of Serialized Data

Key Takeaway:
- 70% of respondents are interested in leveraging serialization data for commercial use/other value-added activities

Plans to Build Serialized Data Analytics Infrastructure

Key Takeaway:
- 90% of respondents have built or have plans to build infrastructure to support analytics of serialization data
- 29% of Manufacturers & 22% of Distributors have built and are analyzing serialization data
Barriers to Realization of Benefits

Key Takeaway:
- 83% of Manufacturers that responded identified visibility to end to end data as a primary barrier
- 72% of Distributors identified cost of implementation and technology
- 100% of Dispensers identified cost of implementation

Conclusion/Recommendations

- A little too early to tell...
- Some good ideas to consider pursuing as organizations develop their implementation plans
- Socialization of the changes coming with DSCSA implementation to cross functional partners may spark additional ideas
- Follow up survey post 2023
Questions?