Impact of Drug Supply Chain Security Act on US Pharmaceutical Industry Under Decentralized Information Flow

Meng Ying Chang, Raghavendran Mohan
Agenda

- Drug Supply Chain Security Act (DSCSA)
- Implementation Solution Design
  - Physical Flow
  - Information Flow
- Supply Chain Impact Evaluation
  - Scenarios
  - Operations Cost
  - IT Investment
  - CAPEX
  - Overall Impact
- Conclusion & Future Research
Fighting Counterfeit Drug

10% of the US pharmaceutical products

$75B business worldwide

50% are sold through websites

60% don’t have active ingredients

17% have inaccurate dosages

16% have incorrect ingredients

* 2011 data source
Drug Supply Chain Security Act (DSCSA)

Serialize Product
- All prescription drugs should have a unique serial# at the unit level

TS/TI/TH
- Records need to be maintained at serial# level when there is a transfer of ownership

FDA Tracing Request
- All requests for records regarding a serial# needs to be addressed within 48 hours
Overview of U.S. Drug Supply Chain

Manufacturer -> Distributor -> Repackager -> Dispenser -> Patient
DSCSA Implementation Timeline

- **JANUARY 1, 2015**
  - Manufacturers send and distributors receive TI/TH/TS + begin direct purchase statement
  - Suspect and Illegitimate Product Requirements Effective

- **JULY 1, 2015**
  - Dispensers receive TI/TH/TS

- **NOVEMBER 27, 2015**
  - National standards for wholesaler distributor licensure issued
  - National standards issued for 3PLs
  - Waiver guidance issued for exchange of TI/TH/TS
  - Standards issued for exceptions to product identifier requirements
  - Standards issued for grandfathering product

- **MAY 1, 2015**
  - TI/TH/TS enforcement discretion ends

- **JANUARY 1, 2015**
  - Wholesale distribution licensure reporting begins
  - Publicly available database of wholesale distributors established by FDA

- **NOVEMBER 27, 2014**
  - Standards published for TI/TH/TS
  - 3PL licensure reporting begins

- **MAY 26, 2014**
  - Draft guidance on suspect product and terminating notification

- **NOVEMBER 27, 2017**
  - Manufacturers serialize product

- **NOVEMBER 27, 2018**
  - Repackers serialize product

- **NOVEMBER 27, 2019**
  - Distributor traceability

- **NOVEMBER 27, 2020**
  - Dispenser traceability

- **NOVEMBER 27, 2023**
  - Unit-level traceability

**KEY**

- **TI** – Transaction Information
- **TH** – Transaction History
- **TS** – Transaction Statement
Implementation Solution Design
Physical Flow

- Unit Level Model
  - All drugs are serialized but there is no mapping to higher UOMs

- Matryoshka Model
Information Flow

Centralized Model

- Manufacturer
- Distribution (Primary)
- Repackager
- Distribution (Secondary)
- Centralized Database
- Pharmacy

Decentralized Model

- Manufacturer
- Distribution (Primary)
- Distribution (Secondary)
- Database
- Pharmacy

TRACK & TRACE WOULD HELP?
To-Be Process Map - Matryoshka Model
To-Be Process Map – Unit Level Model
To-Be Decentralize Data Exchange Model

Data Exchange Model

<table>
<thead>
<tr>
<th>Manufacturer (MF.)</th>
<th>Wholesaler (WS.)</th>
<th>Self. Dist. Dispenser (SDD.)</th>
<th>Dispenser (DS.)</th>
<th>FDA</th>
</tr>
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<tbody>
<tr>
<td>Outgoing Russian</td>
<td>Incoming Supplier</td>
<td>Incoming Supplier</td>
<td>Outgoing Russian</td>
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<tr>
<td>doll info: lot/case/pallet</td>
<td>info</td>
<td>info</td>
<td>info: lot/case/pallet</td>
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Delivery/Transaction

Web Service

Product Info: Serial No.

TH MF. Info: Serial No.

TH WS. Info: Serial No.

TH SDD. Info: Serial No.

Serial No.
Trace back
Supply Chain Impact Evaluation
Evaluation Scenarios

- Centralized information flow with “Matryoshka” nesting of data
- Decentralized information flow with “Matryoshka” nesting of data
- Centralized information flow with unit level data, no nesting
- Decentralized information flow with unit level data, no nesting
Operations Impact - Turnaround time

- Impact on Inbound process is lower as the DSCSA only mandates verification on a sample (10% volume)
- Outbound shipment impact can be reduced by effective inventory management, which is not in scope for this thesis
Decentralised models require least investment and recurring cost as they will be built on existing data interfaces.

Centralised models require most investment as new data exchanges have to be built from scratch.
Financial Impact - CAPEX

- Matryoshka model require more CAPEX in labelling equipment
- Unit level model require less CAPEX from manufacturers and wholesalers
Overall Comparison

<table>
<thead>
<tr>
<th>Cost (10 Years)</th>
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<tbody>
<tr>
<td>Decentralized Unit Level</td>
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<tr>
<td>Decentralized Matryoshka</td>
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<tr>
<td>Centralized (Govt.) Unit Level</td>
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<tr>
<td>Centralized (Govt.) Matryoshka</td>
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<tr>
<td>Centralized (Manuf.) Unit Level</td>
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<tr>
<td>Centralized (Manuf.) Matryoshka</td>
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<tr>
<td>Centralized (3rd party) Unit Level</td>
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Conclusion & Future Research
Conclusion

Advantages of Decentralized Model

- Information flow solution can be built on existing IT infrastructure
- Ensures business privacy and data security for individual players

Least Impact Scenario

- Matryoshka + Decentralized model has least financial impact
- Lower operations cost & IT recurring cost

The Hybrid Reality

- Difficult to standardize implementation across the whole supply chain
- Hybrid model would increase complexity of execution
Future Research

Complexity for Repackager

• Number of units increase significantly.
• Difficulty in mapping inbound serial numbers with outbound serial numbers

New Technology Application

• Implement Cloud service for decentralized data storage
• Apply RFID in product palletization
• Leverage Block Chain to verify incoming data
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