Securing the Drug Supply Chain

A Framework to Evaluate Interoperable Data Exchange Models for Drug Supply Chain Security Act Compliance

Authors: Peter Chung, Tao Zhang
Advisor: André Carrel

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AGENDA

• BACKGROUND
• PROBLEMS
• CONTEXT
• METHODOLOGY
• RESULTS
AGENDA

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BACKGROUND
Drug Security is Important

Embarrassment & Disappointment

Side Effects & Death
BACKGROUND
Drug Security is Decreasing Globally

Source: Pharmaceutical Research and Manufacturers of America
BACKGROUND
New Threats to the US Drug Supply Chain

Challenges
- Counterfeit drugs
- Diverted/illegally imported drugs
- Online drug sales

Solution
Track and trace the smallest sellable unit of drug through the supply chain using serial numbers.

Timeline

<table>
<thead>
<tr>
<th>Disparate State Laws</th>
<th>Data Exchange Standards</th>
<th>Full Compliance of the Industry</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>2023</td>
<td>implementation for Compliance</td>
</tr>
</tbody>
</table>

National Law (DSCSA)
BACKGROUND

Information Flows of the Drug Supply Chain

DSCSA

by 2023

Manufacturers

Distributors

Dispensers

Patients

MIT Supply Chain Management
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PROBLEMS

Numerous Options
- Existing solutions from other countries
- Proposals from domain experts

Multiple Stakeholders
- Manufacturers
- Distributors
- Dispensers
- Patients
- Various Governments

Limited Data
- About operational costs
- From all stakeholders
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**Context**

**Existing Work**
- The HDMA Whitepaper
- The Rx360 Whitepaper

**Evaluation Methods**
- Scorecard

**Strategy Evaluation**
- Tilles (1963)
- Rumelt (1979&1998)
- Perez-Franco (2015)

**Foreign Legislations**
- EU
- Turkey
- Korea & China
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## METHODOLOGY

### Overview

<table>
<thead>
<tr>
<th>Problems</th>
<th>Solutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Numerous Options</td>
<td>Picking One out of Many</td>
</tr>
<tr>
<td>Multiple Stakeholders</td>
<td>A Holistic Approach for Individual Challenges</td>
</tr>
<tr>
<td>Limited Data</td>
<td>Qualitative Analysis of Quantitative Metrics</td>
</tr>
</tbody>
</table>
METHODOLOGY
Picking One out of Many

Categorize for Simplicity

Three types of models

- Centralized
- Semi-centralized
- Distributed
METHODOLOGY
Picking One out of Many

Centralized

Centralized Repository (for a sector and region)

EPCIS Capture Interface

Company A

Company B

Company C
METHODOLOGY
Picking One out of Many

Semi-centralized
METHODOLOGY
Picking One out of Many

Distributed

EPCIS Repository (for company A)
EPCIS Repository (for company B)
EPCIS Repository (for company C)

EPCIS Capture Interface
EPCIS Capture Interface
EPCIS Capture Interface

Company A
Company B
Company C
METHODOLOGY
A Holistic Approach for Individual Challenges

Consolidate concerns from all stakeholders

> Allow information sharing for **compliance**
> Enhance the **operational efficiency**
> Improve patient **safety**
> Protect customer **privacy**
> Balance **international** regulations

COSPI
METHODOLOGY
A Holistic Approach for Individual Challenges

Guide the decision using an extensive framework – SC2020
METHODOLOGY
A Holistic Approach for Individual Challenges

<table>
<thead>
<tr>
<th></th>
<th>Compliance</th>
<th>Operational efficiency</th>
<th>Security</th>
<th>Privacy</th>
<th>International compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company goals and capability</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Corporate guideline</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
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<tr>
<td>Market dynamics</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Industry context</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

High overlap between COSPI and SC2020
METHODOLOGY
A Holistic Approach for Individual Challenges

Mapping Shared Concerns
to Required System Capabilities

COSPI
7 Scenarios
26 Capabilities
4 Types
## METHODOLOGY
Putting Options and Players Together

### Options and Players in One Scorecard

<table>
<thead>
<tr>
<th>Stakeholders</th>
<th>Required Capabilities</th>
<th>Type</th>
<th>Centralized</th>
<th>Semi-centralized</th>
<th>Distributed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer, Distributor and Dispenser</td>
<td>Disclose the information based on the information requester’s privacy access level</td>
<td>A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Grade the privacy level of the submitted information</td>
<td>A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Make serialization data available to verify the authenticity of the drug when the drug is shipped</td>
<td>W/S</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Make sure the verification interface is not compromised (e.g. hacked by fake dealers so that fake drugs can be verified as authentic ones)</td>
<td>W/S</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Map serial number to pallet/case number</td>
<td>R</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Map serial number to the storage space/retail branch</td>
<td>R</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Provide transaction information when transferring ownership</td>
<td>W/S</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Record investigation history</td>
<td>W/S</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
METHODOLOGY
Qualitative Analysis of Quantitative Metrics

Two Types of Costs
> Fixed / Upfront
> Variable / On-going

Qualitative Scores
> Relative favorability
> Non-proportional
> Non-representative

<table>
<thead>
<tr>
<th>Fixed / Upfront Cost</th>
<th>Variable / On-going Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No maintenance effort</td>
</tr>
<tr>
<td>Has cost sharing synergy</td>
<td>5</td>
</tr>
<tr>
<td>No cost sharing synergy</td>
<td>4</td>
</tr>
</tbody>
</table>
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RESULTS

Semi-Centralized Model

- Highest evaluation score
- A balanced mix of flexibility and cost-sharing synergy