U.S. Drug Supply Chain Security Act (DSCSA) and Product Traceability

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April 22, 2015

DSCSA

- Background
- High Level Requirements
- Product Tracing Requirements – 2015
- Suspect and Illegitimate Products
- Lessons Learned
- Summary

Background

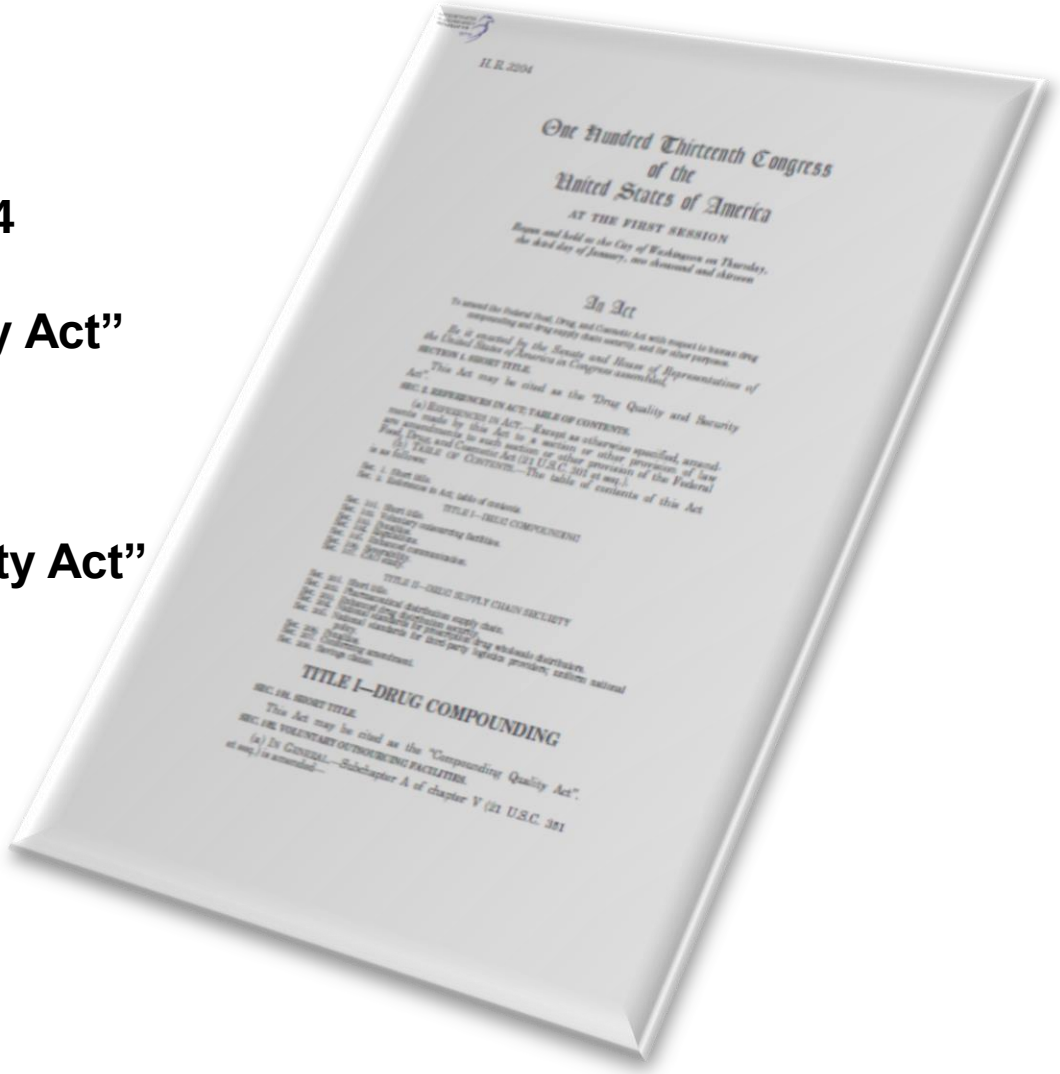
- Counterfeit pharmaceuticals found in the legitimate supply chain
- Increase in cargo theft and diversion
- Patchwork of state pedigree requirements unworkable
- California law required item-level serialization and track-and-trace throughout the supply chain by 2017
- Industry stakeholders collaborated to propose a viable federal solution to legislators that would preempt existing state laws

Drug Quality and Security Act

November 27, 2013
H.R 3204
Public Law No: 113-54

“Drug Quality and Security Act”

Title II
“Drug Supply Chain Security Act”


H.R. 3204

One Hundred Thirteenth Congress
of the
United States of America

AT THE FIRST SESSION

An Act

TITLE I—DRUG COMPOUNDING

Read the original article on the website (http://bigstory.ap.org/article/obama-signs-bill-more-scrutiny-drug-mixers

Drug Supply Chain Security Act

- U.S. federal law – pertains to brand and generic prescription pharmaceuticals
- Human health finished goods (some exceptions) and the legitimate supply chain
- Product tracing, licensing, verification, notification, and serialization requirements
- Change of ownership emphasis
- Phased implementation – all sectors impacted
- State pedigree and licensing preemption
- Alignment with GS1 standards

Drug Supply Chain Security Act
Key Manufacturer's Mandates

2015

Jan 1, 2015

• P**roduct Tracing - (Lot Info)**
Provide for each Change of Ownership:
- •Transaction Info (TI)
- •Transaction History (TH)
- •Transaction Stmt(TS)
- •Single Document
- •Paper or Electronic

•Verification & Sys Requirements
- •Suspect Product
- •Illegitimate Product

•Requests for Information
- •TI, TH, TS ≤ 48 hrs

•Notifications – Illegitimate ≤24 hrs
•Authorized Trading Partners

2017

Nov 2017

•**Serialized Product Identifiers**
- •Each Pkg. and Case
- •2D DataMatrix on Pkg.
- •Linear or 2D on Case
- •NDC + Serial Number (SNI) Lot and Exp Date
- •Human Readable and Machine Readable

•Provide TI,TH,TS in electronic format
•Verification Requirements
- •Product ID/SNI's ≤ 24 hrs
- •SNI for Saleable Returns

•Maintain Product Identifiers – 6 yrs

2023

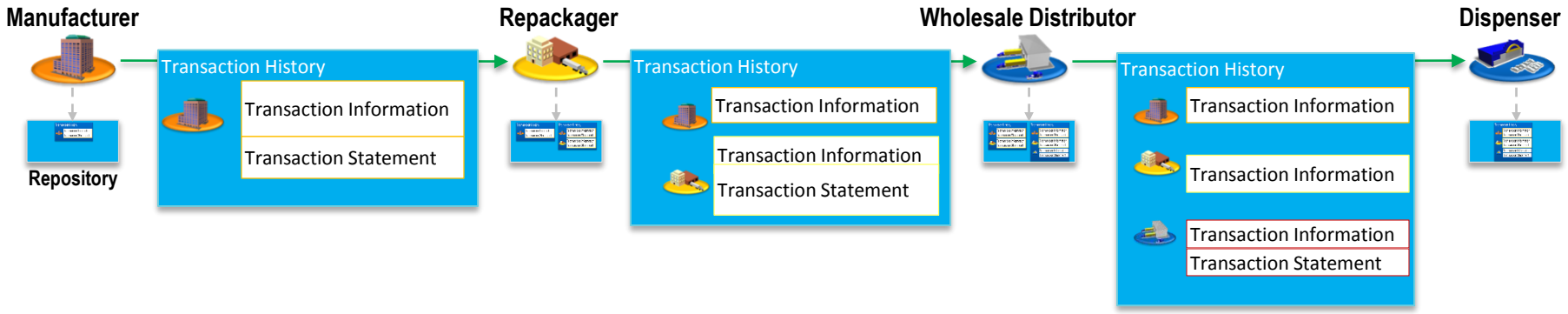
Nov 2023

•**Pkg (Item-level) traceability**
•Interoperable electronic "Tracing"
•Exchange TI, TS in a secure, interoperable electronic manner
•TI to include product identifier
•Systems and Processes for "Verification" of Product at Pkg. level, including the SNI
•Systems and Processes to promptly respond with TI and TS and gather Transaction History
•Saleable Returns – TI and TS
•Requests for Information ≤ 24 hrs

SELF-EXECUTING

Pfizer Global Serialization

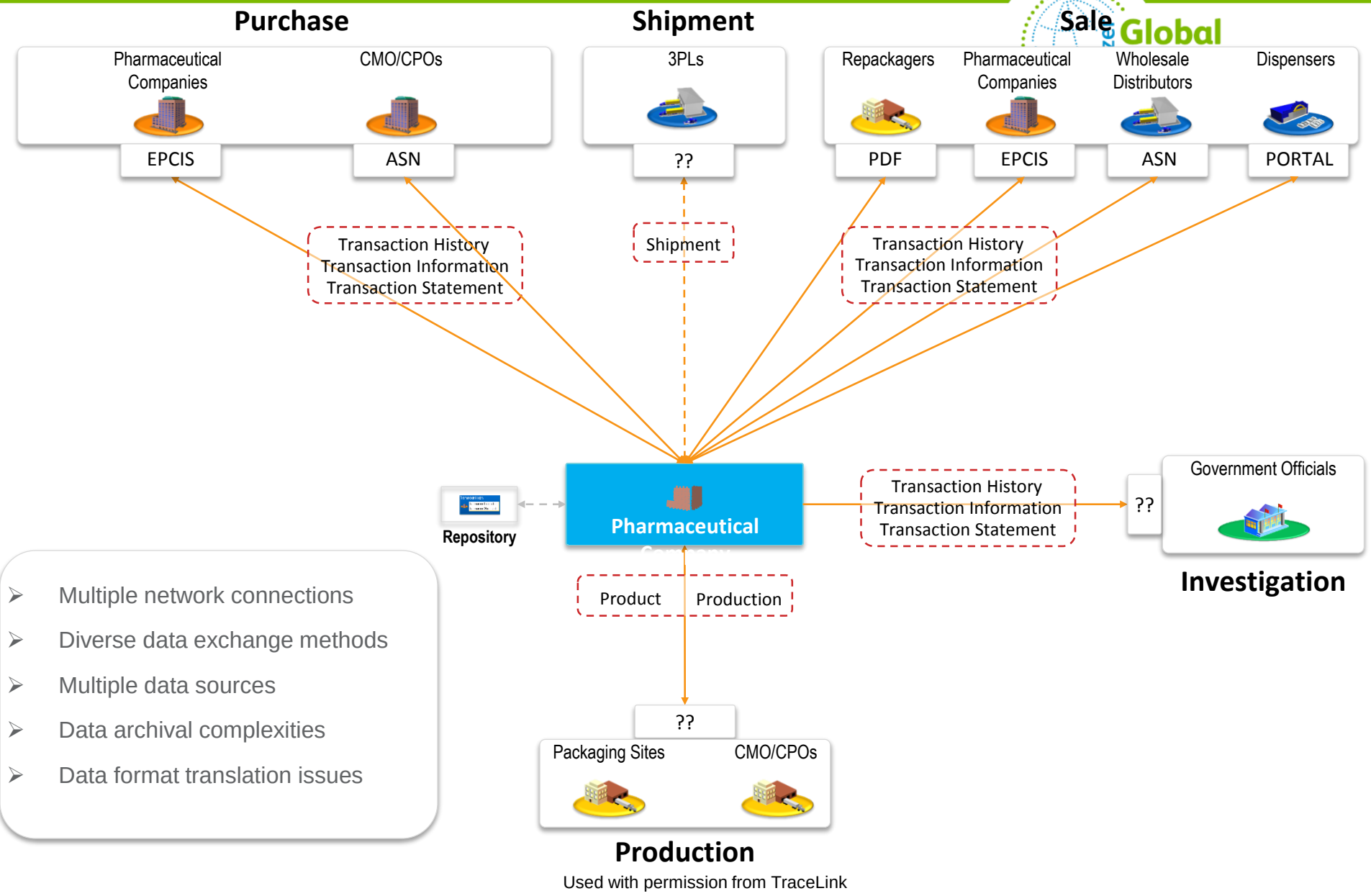
Product Tracing Requirements For 2015



- Acquire or provide on each change of ownership, a single document with:
  - Transaction History + Transaction Information + Transaction Statement
- Compliance documentation required for Sale, Purchase, Drop Shipment, Saleable Returns and retained for 6 years

Transaction History (TH)	Transaction Information (TI)	Transaction Statement (TS)
<u>Single</u> document starting with manufacturer • Includes Transaction Information for each transaction going back to the manufacturer Special versions of Transaction History possible for Direct Purchase wholesale distribution operations Electronic or paper (initially) • Electronic format required starting in 2017	• NDC • Product Name • Strength • Dosage Form • Container Size • Number of Containers • Lot Number (optional in certain scenarios) • Transaction Date (business transaction) • Shipment Date (if >24 hrs. from Trans Date) • Transfer From Party (business name & address) • Transfer To Party (business name & address) • Wholesaler Contact Information (for Drop Shipment)	Statement attesting that party transferring ownership: • Is authorized and registered • Received product from authorized, registered party • Received Transaction Information and a Transaction Statement from the prior owner • Did not knowingly ship suspect or illegitimate product • Had systems and processes in place to comply with verification requirements • Did not knowingly provide false transaction info • Did not knowingly alter the transaction history

Reality of Data Exchange and Network Connection Complexity under DSCSA – PharmaCo Example



- Multiple network connections
- Diverse data exchange methods
- Multiple data sources
- Data archival complexities
- Data format translation issues

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Suspect and Illegitimate Products

- Counterfeit
- Diverted
- Stolen
- Intentionally adulterated such that the product would result in serious adverse health consequences or death to humans
- Subject of a fraudulent transaction
- Appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans

Prescription products in, or intended for, the U.S. legitimate supply chain

Lessons Learned

- Collaboration with industry peers, trading partners, solution providers, standards bodies, regulators and legislators is key
- Connecting all the relevant stakeholders is no small task
- Electronic data exchange is preferred over paper-based solutions
- Implementation takes time even when leveraging existing technology
- Production environment (vs. testing) reveals new challenges
- Traceability has a significant impact on business processes, systems and operations
- A higher level of accuracy/precision is required in daily operations
- Exceptions must be resolved quickly
- Master data issues must be addressed early in the process
- Solution providers play a key role in the successful deployment
- Must implement early and test thoroughly before “go live”
- Start-up, technical issues should be expected

Summary

- U.S. industry stakeholders have made significant progress to comply with the 1/1/15 product tracing and verification requirements
- Technical implementation issues are being addressed
- Product serialization efforts are underway for 2017
- Much work remains to define the 2023 item-level traceability and reporting requirements
- Interoperable system(s) are needed
- Industry and FDA collaboration is essential

Q&A

Thank You!

Contact Information

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