Meeting the Challenges of the New Federal Drug Supply Chain Security Act (DSCSA)

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Agenda

• A brief history of U.S. Pharma Supply Chain Security

• Case Studies:
  • the Heparin debacle
  • the Avastin Case
  • the Levemir Case

• The Federal Drug Supply Chain Security Act (DSCSA)

• Case Studies Revisited

• Implications of the DSCSA
The U.S. Federal PDMA Law

Prescription Drug Marketing Act of 1987

“… Each person who is engaged in the wholesale distribution of drugs […] and who is not an authorized distributor of record of such drugs shall provide to each wholesale distributor of such drugs a statement identifying each sale of the drug (including the date of the sale) before the sale to such wholesale distributor. …”
The Florida Pedigree Law

- Wholesalers must provide “pedigree papers” to customers
- Invoice statement allowed for direct purchases
- Electronic pedigree were allowed optionally
- Buyers were required to authenticate pedigrees
- No serialization required
Wholesalers must provide pedigree papers to customers only if outside “normal distribution” path

“Normal Distribution” was defined by each law

- Typically: Manufacturer → Wholesaler → Pharmacy
- Some: Manufacturer → Wholesaler → Wholesaler → Pharmacy

Pharmacies were typically not required to inspect pedigrees

No serialization required
HDMA Pedigree Regulation Map

Source: HDMA website, February 2013
The California Pedigree Law

Manufacturers were required to serialize Rx drugs and start an *electronic* pedigree

- 50% by 1-1-2015, 100% by 1-1-2-16

Wholesalers and Repackagers were to (by 7-1-2016):

- Read serial numbers at receiving and confirm they received an authentic pedigree
- Update the pedigree and pass it to their customer

Pharmacies were to read serial numbers at receiving and confirm they received an authentic pedigree (by 7-1-2017)
What Were Pedigree Laws Trying To Accomplish Anyway?

• detect the introduction of illegitimate drugs (counterfeit, stolen, up-labeled, diverted, etc.) into the legitimate supply chain as early as possible, preferably at the very first transaction

• identify who participated in the introduction of the illegitimate product

• Help prosecute criminals efficiently by automatically generating solid evidence

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The Heparin Debacle

- First recall issued January 17, 2008
- Over 80 lots from 25 different NDCs eventually recalled
- Supply chain was overwhelmed by the recalls, allegedly resulting in “circular” shipments

Number of deaths reported during Heparin use, Jan '07 to May '08

![Chart showing number of deaths reported during Heparin use from January 2007 to May 2008.]

Source: FDA website

*The death reports in this chart concern heparin produced by any manufacturer. Counts indicate the month the death was reported which may differ from the month the death actually occurred.
The Avastin Case

Occurred in 2012

Potential path of counterfeit drugs that matches alleged path documented by U.S. FDA and in Reuters “Fake Avastin's path to U.S. traced to Egypt” article
The Levemir Case

- Theft occurred February 5, 2009 in North Carolina
- Drug was dispensed to patients in four states less than 3 months later
- Uncovered due to adverse reactions in patients

Hypothetical path of stolen drugs that matches alleged path documented in “Drug Theft Goes Big”

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The Drug Supply Chain Security Act (DSCSA)

• Drug Quality and Security Act (DQSA) signed by President Obama on November 27, 2013
  • The DSCSA is “Title II” within the DQSA
• Passage resulted in the immediate preemption of all State drug pedigree and serialization laws
  • Federal PDMA terminates on Jan 1, 2015
• New detailed Federal regulations will take effect in 2015, 2017, 2018, 2019, 2020, and 2023
• Implements a “lot-based pedigree” system until 2023 when it becomes a serialization-based, “records retention” system
DSCSA Table of Contents

• Definitions (Definition of terms used in DSCSA)
• Requirements
  • General (Instructions to the FDA)
  • Manufacturer Requirements
  • Wholesale Distributor Requirements
  • Dispenser Requirements
  • Repackager Requirements
• Enhanced Drug Distribution Security (2023)
• National Standards for Drug Wholesale Distributors
• National Standards for Third-Party Logistics Providers
• Uniform National Policy
• Penalties
FDA Responsibilities

- Guidance documents
  - Identification of suspect product and notification steps
  - Standards for interoperable exchange of transaction data
  - Processes for waivers, exceptions and exemptions
  - Grandfathering product
  - System attributes for secure tracing at package level
- Conduct at least 5 public meetings
- Conduct at least 1 pilot projects with industry
- New wholesaler and 3PL licensing system
- New regulations for enhanced distribution security
- “Suspect Product” investigations
Summary of Planned Implementation Timeframes for the Drug Supply Chain Security Act

Date of enactment: November 27, 2013
Published by FDA: February 20, 2014

- Issue notice of public docket to collect stakeholder comments on standards for interoperable exchange of transaction information/history/statement in paper or electronic format
- Publish guidance on identification of suspect product and termination of notifications of illegitimate product for finished human prescription drugs
- Publish draft guidance establishing standards for interoperable exchange of transaction information/history/statement in paper or electronic format
- Establish a system for third-party logistic provider reporting to FDA
- Establish a system for wholesale drug distributor reporting to FDA and public database for licensing information
- Develop regulations establishing standards for licensing of wholesale distributors
- Develop regulations establishing standards for licensing of third-party logistic providers
- Publish guidance on processes of waivers, exceptions, exemptions
- Publish final guidance on grandfathering product
- Conduct at least 5 public meetings
- Establish 1 or more pilot projects in coordination with stakeholders to explore and evaluate methods to enhance the safety and security of supply chain
- Conduct and complete a technology software assessment on feasibility of small dispensers to conduct drug tracing at the package level
- Publish final guidance on system attributes necessary to enable secure tracing at the package level
- Publish final guidance on the standards for interoperable data exchange to enhance secure tracing of product at the package level
- Develop regulations establishing enhanced drug distribution security system for interoperable electronic tracing of product at the package level
Manufacturers: Serialization

• Manufacturers must apply a 2D barcode on each package and homogeneous case by November 27, 2017
• The barcode must encode the drug’s:
  • NDC,
  • serial number,
  • lot and
  • expiration date
• The serial number will be present after that date but will *not be used* until 2023, except when investigating suspect product
“Lot-based pedigree” System

For the first 10 years, the DSCSA implements a **lot-based pedigree system**

That is, for each drug in a shipment, most sellers of drugs in the supply chain will be legally obligated to provide buyers with specific:

- “Transaction Information”,
- “Transaction History”, and
- “Transaction Statements”

The data does NOT include serial numbers but is at the lot level. This data may be provided in either paper or electronic format.* This data must be retained and retrievable within 48 hours for 6 years after the transaction

* Manufacturers must provide this data electronically in 4 years, except when selling directly to a practitioner
Dispensers

Starting July 2015:
“...shall not accept ownership of a product unless the previous owner, prior to, or at the time of the transaction, provides **transaction history, transaction information, and a transaction statement**”

“prior to, or at the time of, each transaction in which the dispenser transfers ownership of a product (but not including dispensing to a patient, or returns) shall provide the subsequent owner with **transaction history, transaction information, and a transaction statement** for the product...”
Transaction Information

- The proprietary or established name or names of the product;
- The strength and dosage form of the product;
- The National Drug Code (NDC) number of the product;
- The container size;
- The number of containers;
- The lot number of the product;
- The date of the transaction;
- The date of the shipment, if more than 24 hours after the date of the transaction;
- The business name and address of the person from whom ownership is being transferred; and
- The business name and address of the person to whom ownership is being transferred.
Transaction History

• A statement in paper or electronic form, including the Transaction Information for each prior transaction going back to the manufacturer of the product,

• …except, when provided by a wholesale distributor who bought the drug directly from the manufacturer, the Transaction History may not include the lot number of the product, the initial transaction date or the initial shipment date from the manufacturer. In that case, the Transaction Statement from the wholesale distributor must indicate that the drug was acquired directly from the manufacturer.
Transaction Statement

A statement, in paper or electronic form, that the entity transferring ownership in a transaction:

A. is “authorized”;
B. received the product from a person that is “authorized”
C. received “transaction information” and a “transaction statement” from the prior owner of the product;
D. did not knowingly ship a “suspect product” or “illegitimate product”;
E. had systems and processes in place to comply with DSCSA “verification” requirements;
F. did not knowingly provide false “transaction information”;
G. did not knowingly alter the “transaction history”; and
H. In some cases, an indication that the entity, or an affiliate, purchased the product directly from the manufacturer, exclusive distributor or repackager that purchased the product directly from the manufacturer.
Returns

Dispensers will not need to provide Transaction Information, Transaction History or Transaction Statements when returning products to the company they acquired them from.
Verification

Starting *next January*, all members of the supply chain must have systems in place to enable proper handling of suspect product:

- Quarantine
- Investigation
- Clearing suspect product
- Record-keeping
- Notifications when illegitimate product is found
- Responding to request for information
After 10 years (November 2023)

DSCSA transforms into a one-up, one-down transaction records retention requirement that is based on package-level serial numbers:

• Transaction Histories will no longer be required
• Serial numbers must be included in the Transaction Information
• Transaction Information and Transaction Statements must be exchanged in a secure, interoperable, electronic manner according to FDA standards that are currently TBD
• The data must be retrievable within 24 hours
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How the DSCSA Will Prevent Events Like The Heparin Debacle

• The DSCSA will not prevent economically motivated adulteration of drugs by API manufacturers

• But it will greatly enhance the speed, efficiency and accuracy of recall execution

• The 2D barcode on all packages and homogeneous cases will contain the lot number so inventory and WMS applications can check for recalled lots automatically at every step in the supply chain, making circular distributions much less likely

• Requires voluntary software changes!
How The DSCSA Will Prevent Cases Like The Avastin Case

The DSCSA may not have much impact on cases like this because the crime takes place so close to the end of the supply chain. The importer/distributor and the dispensers who bought the Avastin participated in the crime. From now on, it will be a crime not to have the DSCSA transaction data on file for all drugs bought/sold/dispensed. Perhaps the new scrutiny by the FDA on supply chain crimes brought on by the passage of the DSCSA will have a deterrent effect on these criminals.
How The DSCSA Will Prevent Cases Like The Levemir Case

The DSCSA may not have much impact on cases like this except as a **deterrent**. The pedigree and record-keeping will ensure that once suspect drugs are detected, the investigation will proceed quickly and accurately. Criminals may not be willing to expose themselves to almost certain arrest shortly after an investigation is begun.

Transaction data (Pedigrees) may be easy to forge, but a forged pedigree is great evidence for use against the forger.
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DSCSA and the FDA

• This is the first time the FDA has ever needed to understand and regulate any part of the finished goods supply chain.
• They will need new skills and knowledge, and additional people to fulfill their newly expanded mission.
• Expect them to start out slow and act tentatively while they acquire the necessary resources and training.
• Look for another possible User Fee Act (UFA) to establish the fees for wholesale distributor and third-party logistics provider licenses as hinted at in the DSCSA
Repurposing California Solutions

• Manufacturers will find it easy to convert their California serialization solutions to meet the serialization requirements of the DSCSA

• However, ePedigree solutions deployed by manufacturers, wholesale distributors, repackages and dispensers for California and other pedigree laws will require significant changes and may not be worth converting for use to meet the DSCSA

• More than likely, the industry will rally around the use of EDI for the electronic exchange of transaction data
Will The DSCSA Exacerbate Shortages?

FDA is required to include a process for companies to apply for waivers, exemptions and exceptions to individual requirements, and they are likely to grant one if it would otherwise lead to a shortage.

On the other hand, the incremental cost increase for serialization and data collection, retention and access could cause some manufacturers to trim marginally profitable products, which could lead to more shortages.
Will Today’s Linear Barcode Go Away in 2017?

- Probably not immediately, but a few years after that, yes
- Watch for the FDA to begin preparing for the switch soon
- Bottom line: *Do not buy any more linear barcode readers!*
Data Visibility

There are somewhat confusing sections in the DSCSA that discuss data visibility and confidentiality for wholesale distributors and dispensers.

Interested parties should review sections:

- Wholesale distributor:
  - 582(c)(1)(A)(v)(II) Confidentiality of transaction information
  - 582(c)(1)(D) Trading Partner Agreements (starting in 2019)
  - 582(k)(3), which changes the effect of the wholesale distributor provisions above after 10 years

- Dispensers:
  - 582(d)(1)(B) Agreements With Third Parties
DSCSA Explained—Coming Soon

New E-book from Dirk Rodgers of RxTrace
• Translates the DSCSA legalese into English
• Explains the significance of key sections
• Provides quick links to the original DSCSA text and key definitions throughout
• An essential resource for anyone who needs to understand the DSCSA provisions
  • Senior Leadership
  • Quality and Regulatory
  • Supply Chain Operations
  • IT
  • Implementation Project Managers
  • Solution Providers
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