Keynote Presentation: DSCSA Update

Speaker: Connie T. Jung, RPh, PhD
Acting Associate Director for Policy & Communications, Office of Drug Security, Integrity & Recalls, Office of Compliance, Center for Drug Evaluation and Research, U.S. Food and Drug Administration
Drug Supply Chain Security Act
(Title II of the Drug Quality and Security Act)
Implementation Update

Connie Jung, RPh, PhD
U.S. Food and Drug Administration

HDMA 2014 Traceability Seminar
November 11, 2014
Getting Ready for the DSCSA

• Become familiar with the law
• Understand stakeholder responsibilities
• Become familiar with statutory dates of the law
• Check our FDA website - The DSCSA web page
  – Overview
  – Implementation Plan
  – Links to FDA webinar(s)
  – FDA DSCSA Public Workshop (May 8-9, 2014)
  – Updates
• Get engaged in discussions
Objectives

• Overview of the Drug Supply Chain Security Act
• Product Tracing Requirements
• Wholesale Drug Distributor and Third-Party Logistics Provider Provisions
• Implementation Updates
DSCSA
The Drug Supply Chain Security Act

What is it?
Drug Quality Security Act (DQSA)

Title I: The Compounding Quality Act

Product Tracing

Title II: Drug Supply Chain Security Act (DSCSA)

Wholesale Distributor and 3PL Licensing and Standards
Overview of the DSCSA (enacted 11/27/2013)

- Product tracing
- Product verification
  - Quarantine and investigation (steps for detection and response)
  - Notification
  - Recordkeeping
- Product identification
- Wholesaler standards for licensure
- Third-party logistics provider standards for licensure
- Enhanced system – 10 years
- Penalties
- National uniform policy
Stakeholders Involved

- Dispenser
- Manufacturer
- Repackager
- Third-party logistics provider
- Wholesale distributor
- FDA
- State officials
- International regulatory counterparts
- Others
Definitions

- Dispenser
- Distribute
- Illegitimate product
- Manufacturer
- Package
- Product
- Product identifier
- Quarantine
- Repackager
- Return

- Standardized numerical identifier
- Suspect product
- Trading partner
- Transaction
- Transaction history
- Transaction information
- Transaction statement
- Wholesale Distributor
- Among others…
Definitions: Scope

**Product**
- **What’s covered:**
  - Prescription drug in finished dosage form for administration to a patient without further manufacturing (such as capsules, tablets, lyophilized products before reconstitution)
- **What’s not covered:**
  - Blood or blood components intended for transfusion
  - Radioactive drugs or biologics
  - Imaging drugs
  - Certain IV products
  - Medical gas
  - Homeopathic drugs
  - Lawfully compounded drugs

**Transaction**
- Transfer of product where a change of ownership occurs
- **Exempt**
  - Intercompany distributions
  - Distribution among hospitals under common control
  - Public health emergencies
  - Dispensed pursuant to a prescription
  - Product sample distribution
  - Blood and blood components for transfusion
  - Minimal quantities by a licensed pharmacy to a licensed practitioner
  - Charitable organizations
  - Distributions pursuant to a merger or sale
  - Certain combination products
  - Certain medical kits
  - Certain IV products
  - Medical gas distribution
  - Approved animal drugs
Product Tracing

• Beginning 1/1/2015, manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies beginning 7/1/2015) in the drug supply chain will provide information about a drug and who handled it each time it is sold in the U.S. market.

• This transaction documentation consists of:
  – Transaction information (TI) which include lot number of product (except for certain wholesale drug distributor transactions)
  – Transaction history (TH)
  – Transaction statement (TS)

• FDA is required to establish standards for the exchange of transaction documentation no later than 11/27/2014.
Definitions: Transaction Information, History, and Statement

**Transaction Information (TI):**
- Proprietary or established name or names of the product;
- Strength and dosage form of the product;
- National Drug Code number of the product;
- Container size;
- Number of containers;
- Lot number of the product;
- Date of the transaction;
- Date of the shipment, if more than 24 hours after the date of the transaction; and
- Business name and address of the person from whom and to whom ownership is being transferred.

**Transaction History (TH):** A statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.

**Transaction Statement (TS):** A statement, in paper or electronic form, that the entity transferring ownership in a transaction—
- Is authorized as required under DSCSA;
- Received the product from a person that is authorized as required under DSCSA;
- Received transaction information and a transaction statement from the prior owner of the product, as required under the law;
- Did not knowingly ship a suspect or illegitimate product;
- Had systems and processes in place to comply with verification requirements under the law;
- Did not knowingly provide false transaction information; and
- Did not knowingly alter the transaction history.
Authorized Trading Partners

- **Manufacturers and Repackagers**: valid registration with FDA
- **Wholesale distributors**: valid State or Federal license and compliance with reporting requirements; considered authorized before federal licensing regulations effective if possesses “valid license under State law”
- **Third-party logistic provider**: valid State or Federal license and compliance with reporting requirements; considered authorized before federal licensing regulations effective, unless FDA makes certain findings and gives notice
- **Dispensers**: valid State license

Beginning 1/1/2015 - trading partners must be “authorized”
Product Verification

No later than 1/1/2015, manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) shall establish systems and processes to be able to comply with the verification requirements.

Definitions

Suspect Product - reason to believe that the product is potentially:
  - Counterfeit, diverted, stolen
  - Subject of fraudulent transaction
  - Intentionally adulterated or appears otherwise unfit for distribution such that would result in serious adverse health consequences or death to humans

Illegitimate Product - credible evidence that the product actually is any of the above
Product Identification (Serialization)

• No later than 4 years (11/27/2017), manufacturers, followed by repackagers (11/27/2018) shall place a unique product identifier on certain prescription drug packages
  – 2D bar code
• Product identifier
  – National Drug Code
  – Serial number
  – Lot number
  – Expiration date
• After 6 years (11/27/2019), wholesalers, followed by dispensers (11/27/2020), will only trade products with product identifiers.
• Verification requirements change once product is serialized. (starting in 2017 for M, 2018 for R, 2019 for WD and 2020 for D)
Wholesaler Licensing and Standards

• No later than 11/27/2015, FDA is required to develop new federal standards for licensing of wholesale drug distributors and a federal system for wholesale drug distributor licensing for use when a state system does not meet federal standards.
• Beginning 1/1/2015, wholesale drug distributors shall report their licensing status and contact information to FDA. This information will then be made available in a public database.
• Coordination with appropriate state officials
Third-Party Logistics Provider (3PL) Licensing and Standards

• No later than 11/27/2015, FDA is required to develop new federal standards for licensing of 3PLs and a federal system for 3PL licensing for use when a state system does not meet federal standards.

• The licensing regulations go into effect 1 year after regulations are finalized. At that time, 3PLs are required by federal law to obtain a state or federal license.

• Beginning 11/27/2014, 3PLs shall report their licensing status and contact information to FDA.
Enhanced System – 10 years

• Establishes package level requirements for the interoperable, electronic tracing of products that shall go into effect 10 years after enactment of this Act, including those relating to:
  – Electronic exchange of transaction information for each sale of certain prescription drugs
  – Verification of product identifiers at the package level
  – Prompt response to suspect and illegitimate products when found
  – Improved efficiency of recalls
Uniform National Standards

• Product tracing and other requirements:
  – No state or local government may establish or continue in effect requirements for tracing products through the distribution system which are inconsistent with, more stringent than, or in addition to, any requirements applicable under 503(e) (as amended by such Act) or the subchapter, or which are inconsistent with any waiver, exception, exemption, or restrictions under sections 581 or 582.

• Wholesale distribution and 3PL standards:
  – Prohibits any state or local government from establishing or continuing any standards, requirements, or regulations with respect to the licensing of wholesale prescription drug distributors or 3PLs that are inconsistent with, less stringent, directly related to, or covered by standards and requirements applicable under section 503(e) (as amended by such Act) or section 584 (for 3PLs).
  – No state shall regulate 3PLs as wholesale distributors
DSCSA
The Drug Supply Chain Security Act

Product Tracing
Product Tracing

• Beginning 1/1/15, manufacturers, wholesaler drug distributors, repackagers, and many dispensers (beginning 7/1/15) must provide TI, TH, TS to the subsequent owner for each transaction (which change of ownership occurs)

  Note: Dispensers do not need to provide this information to patients pursuant to a prescription.

• Transaction documentation consists of:
  – Transaction information (TI)
  – Transaction history (TH)
  – Transaction statement (TS)

• TI includes lot number of product (except for certain wholesale drug distributor transactions)
Product Tracing

Accepting ownership

Beginning 1/1/15, wholesaler drug distributors, repackagers, and many dispensers (beginning 7/1/15) cannot accept ownership of a product, unless the previous owner, prior to, or at the time of, the transaction provides TI, TH, and TS for the product.

Record keeping (capturing and maintaining information)

- Manufacturers and repackagers shall capture TI (including lot level information), TH, TS for each transaction and maintain such information, history and statement for not less than 6 years (record keeping requirement).

- Wholesaler distributors shall capture TI (including lot-level information as described in the law), TH, TS and maintain for not less than 6 years.

- Dispensers shall capture TI (including lot-level information, if provided), TH, TS as necessary to investigate suspect product for at least 6 years (record keeping requirement).
Product Tracing

Manufacturer Specific

Manufacturers -

- Shall provide to subsequent owner TI, TH, and TS, prior to, or at the time of each transaction (transfer of product with change of ownership) of a product, in a single document (paper or electronic).

- Beginning 11/27/17, shall provide TI, TH, TS in electronic format. **Exception:** may continue to use paper format to licensed health care practitioners authorized to prescribe medication under State law or other licensed individual under the supervision or direction of such a practitioner who dispenses product in the usual course or professional practice.
Product Tracing

Wholesale Distributor Specific (1)

- If a WD purchased directly from the manufacturer (M), the exclusive distributor (ED), or repackager (R) that purchased directly from M –
  - “direct purchase statement” provided to the subsequent purchaser
  - TH and TI are not required to include lot number of product, initial transaction date, or the initial shipment date from the manufacturer as defined in section 582(26)
  - TI, TH, and TS provided to a dispenser shall be in a single document in paper or electronic format
  - TI/TH, TS shall be provided to subsequent WDs, but can be in any combination of self-generated paper, electronic data, or manufacturer-provided information on the product package.
Product Tracing

Wholesale Distributor Specific (2)

- If the WD **did not purchase a product directly** from the M, ED, or an R that purchased directly from the M, then prior to or at the time of transaction or subsequent transaction, the WD shall provide to the subsequent purchaser a TI, TH, and TS in paper or electronic format that complies with the initial standards guidance FDA publishes.

- For this WD, the TH will begin with the WD that purchased directly from M, ED, or an R that purchased directly from the M, and this WD will inform subsequent purchasers that it received a direct purchase statement from the WD that purchased directly from M, ED, or an R that purchased directly from the M.

- Shall maintain the confidentiality of the transaction information, history and statement in a way that prohibits disclosure to any person, with a few exceptions (for example, when sharing with State or Federal officials).
Dispenser Specific

Dispensers (Pharmacies) -

• May enter into a written agreement with a third party, who confidentially maintains the TI, TH, TS on behalf of the dispenser (could be an authorized wholesale distributor).

• Shall maintain a copy of the written agreement.

• Are not relieved of obligations of the dispenser.
Product Verification

• No later than 1/1/15, manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) shall establish systems and processes to be able to comply with the verification requirements
  – Must be able to respond to verification requests from Secretary about suspect product
  – Quarantine and investigate suspect product to determine if illegitimate product (includes validating applicable TI and TH)
  – Notify trading partners and FDA of illegitimate product (within 24 hours of determination)
  – Respond to notifications of illegitimate product
  – Recordkeeping

• Verification requirements change once product is serialized.
  (starting in 2017 for M, 2018 for R, 2019 for WD and 2020 for D)
Request for Information

When responding to requests for information from FDA or other appropriate Federal or State official in the event of a recall or for the purpose of investigating a suspect or illegitimate product,

• **Manufacturers, Wholesale Distributors, Repackerager:**
  
  Shall provide applicable TI, TH, and TS, not later than 1 business day, not to exceed 48 hours after receiving request.

• **Dispensers:**
  
  Shall provide applicable TI, TH, TS not later than 2 business days (or another reasonable time as determined by FDA) after receiving request; shall not include lot, initial transaction date or initial shipment date unless such information was provided; may respond in paper or electronic format; certain limitations to information requests apply until November 27, 2017.
DSCSA
The Drug Supply Chain Security Act

Wholesale Drug Distributor and Third-Party Logistics Provider Provisions
Definitions

WHOLESALE DISTRIBUTOR — a person (other than a manufacturer…) engaged in wholesale distribution (as defined in section 503(e)(4))

- Wholesale Distribution is defined as the distribution of a drug… to a person other than a consumer or patient, or receipt of a drug… by a person other than the consumer or patient

- Contains a number of exceptions for example: intracompany distribution, transfers to and from third-party logistics providers and common carriers, distribution of certain drugs in medical convenience kits, IV fluid replenishment and dialysis drugs, medical gases, etc.

THIRD-PARTY LOGISTICS PROVIDER — entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.
Wholesaler licensing and standards

• FDA shall develop regulations establishing standards for licensing for Wholesale Distributors (WD) by 11/27/2015.

• WD standards for licensure go into effect 2 years (11/27/2017) after regulation are finalized.

• The federal system for wholesale drug distributor licensing shall be used when the state from which the drug is distributed has not established a licensure requirement.
Third-party logistics provider (3PL) licensing and standards

• No state shall regulate 3PLs as wholesale distributors.

• FDA shall develop regulations establishing standards for licensing for Third-Party Logistic Providers by 11/27/2015.

• 3PL standards for licensure go into effect 1 year (11/27/2016) after regulations are finalized.

• At that time, 3PLs are required by federal law to obtain a state or federal license.

• The federal system for 3PL licensing shall be used when the state from which the drug is distributed has not established a licensure requirement.
Wholesaler and 3PL Reporting to FDA

<table>
<thead>
<tr>
<th>Who</th>
<th>When</th>
<th>Frequency</th>
<th>What</th>
</tr>
</thead>
<tbody>
<tr>
<td>3PL</td>
<td>11/27/2014</td>
<td>annually</td>
<td>Licensing status and contact information</td>
</tr>
<tr>
<td>WD*</td>
<td>1/1/2015</td>
<td>annually</td>
<td>Licensing status, contact information, significant disciplinary actions</td>
</tr>
</tbody>
</table>

*FDA is required to establish a database of authorized wholesale distributors which will include licensing status and contact information and be available to the public on FDA’s website.
Wholesaler Reporting to FDA

FDA Public Database - established no later than 1/1/2015

Coordination – FDA shall establish a format and procedure for appropriate State officials to access the information in the database in a prompt and secure manner.

- State and license #
- Facility information, including all trade names
- Significant disciplinary actions such as revocation or suspension of license
DSCSA
The Drug Supply Chain Security Act
Implementation Updates
Drug Supply Chain Security Act

Public Workshop | May 8-9, 2014

Standards for the interoperable exchange of tracing information for finished, human, prescription drugs
Goals of the Workshop

• To obtain input from workshop participants on how trading partners can best comply with the requirements for the interoperable exchange of transaction information, transaction history, and transaction statements under the DSCSA on January 1, 2015 using currently available standards or practices.

• To utilize this input to help FDA establish initial standards for the interoperable exchange of transaction information, transaction history, and transaction statements in paper or electronic format that will be issued in the draft guidance required under Sec. 203 (h) of the DSCSA.

For discussion purposes only. Developed for use at this public workshop. This information should not be interpreted as a final decision or position of FDA.
Draft Guidance: Identification of Suspect Product and Notification

• Published on 6/11/2014
• Describes scenarios that increase risk of suspect product for entering supply chain
• Recommendations on how to identify and make determination of suspect product
• Sets forth process to notify FDA and consult with FDA to termination notifications about illegitimate product


- Comment period ended 8/11/2014
- Proposes draft form FDA 3911: Drug Notification
- Comments are under review
Drug Notification

1. Type of Report (Select one):
   - Initial Notification
   - Follow-Up Notification
   - Request for Termination

2. Date of Initial Notification (mm/dd/yyyy)
3. Date Illegitimate Product Was Determined by Company (mm/dd/yyyy)
4. Classification of Notification (Select from list)

Description of Illegitimate Product

5. Generic Name
6. Trade Name (If applicable)

7. Drug Use (Select from list)
8. Drug Description (Select from list)
9. Strength of Drug
10. Dosage Form (Select from list)

11. Quantity Of Drug (Number and Unit)
12. NDC Number (If applicable)
13. Serial Number (If applicable)

14. Lot Number(s)
15. Expiration Dates

16. For Notification: Description of event/issue

17. For Request for Termination of Notification: Description of why notification is no longer necessary

18. If you have submitted information to FDA through an alternative mechanism, check all that apply:
   - BDPR
   - MedWatch 3500
   - None
   - FAR
   - MedWatch 3500A
   - Other (Specify):

This section applies only to requirements of the Paperwork Reduction Act of 1980.

"DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS.

The burden time for this collection of information is estimated to average 1 hour per response.

The time to complete this form includes the time to review instructions, search existing data sources, gather and maintain the data needed, and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
The Effect of Section 585...

- Q&A Guidance for Industry; published on 10/8/2014

- To assist industry and State and local governments in understanding the effects of section 585 of the FD&C Act
  - immediate effects of the law
  - clarify effect on State product tracing and standards and requirements for wholesale distributor and third-party logistics provider licensing

- Section 585 sets forth uniform national policy preemption States from establishing or continuing in effect certain standards and requirements
Uniform National Policy

• Product tracing and other requirements:
  – No state or local government may establish or continue in effect requirements for tracing products through the distribution system which are inconsistent with, more stringent than, or in addition to, any requirements applicable under 503(e) (as amended by such Act) or the subchapter, or which are inconsistent with any waiver, exception, exemption, or restrictions under sections 581 or 582.

• Wholesale distribution and 3PL standards:
  – Prohibits any state or local government from establishing or continuing any standards, requirements, or regulations with respect to the licensing of wholesale prescription drug distributors or 3PLs that are inconsistent with, less stringent, directly related to, or covered by standards and requirements applicable under section 503(e) (as amended by such Act) or section 584 (for 3PLs).
  – No state shall regulate 3PLs as wholesale distributors
THANK YOU!

Comments or questions to:

drugtrackandtrace@fda.hhs.gov
or
wdd3plrequirements@fda.hhs.gov