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Drug Supply Chain Security Act
(Title II of the Drug Quality and Security Act)

Taking a Step To Further Protect Public Health

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2014 PDA/FDA Pharmaceutical Supply Chain Conference
June 4, 2014

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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

2

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Stakeholders Involved

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

3

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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...

4

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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

5

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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.

6

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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.

7

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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"

8

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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

9

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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)

10

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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

11

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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.

12

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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

13

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Uniform National Standards - Preemption

- 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

14

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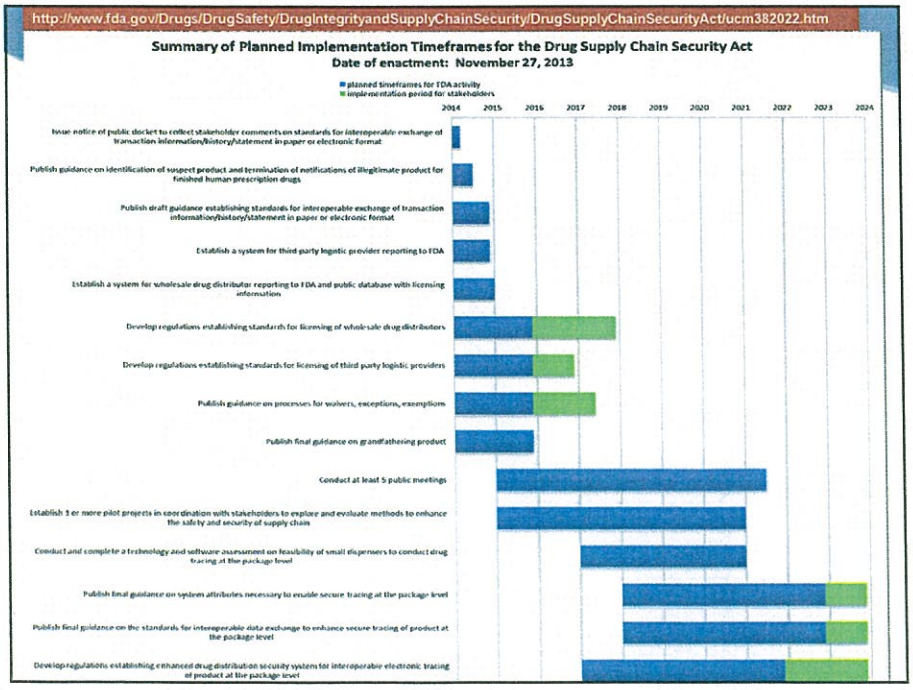
DSCSA Implementation Plan

- The law requires FDA to develop standards, guidances, regulations, pilot programs, and licensing programs and hold public meetings and other efforts to support efficient and effective implementation of the law.

- FDA Offices involved in the implementation
  - Center for Drug Evaluation and Research (CDER) - LEAD
  - Center for Biologics Evaluation and Research (CBER)
  - Office of Regulatory Affairs (ORA)
  - Office of the Commissioner (OC)
    - Office of Chief Counsel
    - Office of Policy/Office of Planning
    - Office of External Affairs

15



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DSCSA

The Drug Supply Chain Security Act

Initial steps

17

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Standards for interoperable exchange of information in paper or electronic format

- FDA docket established 2/20/2014 to accept comments from interested stakeholders
- Questions seeking information about current practices, research, and ideas for:
  - interoperable exchange of transaction information/history/statement (TI/TH/TS)
  - providing, receiving, and terminating notifications
  - requests for verification, and
  - responding to requests from FDA or other Federal/State officials

18

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Drug Supply Chain Security Act

Public Workshop | May 8-9, 2014

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

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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.

20

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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)

21

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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).*

22

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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.

23

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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" becomes the transaction statement for this WD
  - 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.

24

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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).

25

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Product Tracing

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.

26

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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, Repackager:**

  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.

27

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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)

28

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What We Heard

- Flexibility, with structure
- Trading partners, varying degrees of sophistication
- Electronic preferred, paper needed
- Issue guidance ASAP, stakeholders moving forward in the meantime
- Great opportunity for dialogue with all stakeholders at the table
- Clarification (examples – not inclusive)
  - Name of Product
  - Strength
  - Dosage form
  - NDC
  - Container Size
  - Date of transaction
  - Date of shipment
  - Business name & address

29

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Summary of Supply Chain Options

For transactions between manufacturers or repackagers and wholesale distributors and transactions between wholesale distributors and dispenser –

- EPCIS (Electronic Product Code Information Services)
- EDI (Electronic Data Interchange)/(Advance Ship Notice)
- Web portal
- Package slip

- Invoice
- Email

...are the tools that could be used to meet the requirements

30

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Public Workshop Webpage

http://www.fda.gov/Drugs/NewsEvents/ucm388993.htm

Workshop Materials

- Agenda
- Discussion Topics
- Slides
- Recorded portions
- Workshop summary

31

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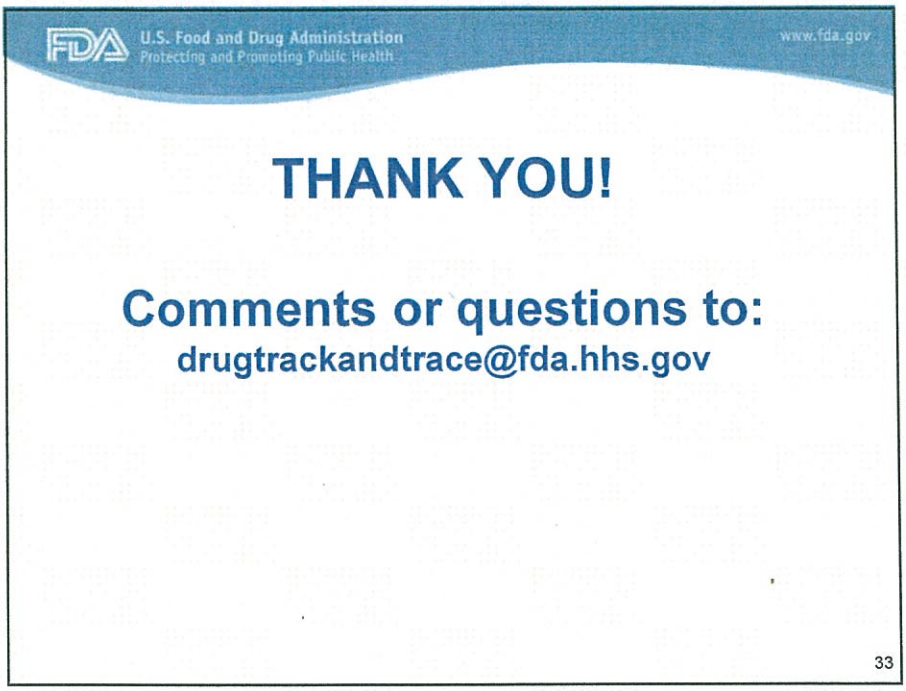
How to submit comments to the docket

- Submit electronic comments to http://www.regulations.gov .
- Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- All comments should be identified with the docket number FDA-2014-N-0337.
- Public workshop docket will close on June 9, 2014.
- Stakeholder input essential and valued!

32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33