Enhanced Drug Distribution Security – Drug Supply Chain Security Act (DSCSA) Implementation Updates

Connie T. Jung, RPh, PhD
Captain, US Public Health Service
Office of Drug Security, Integrity, and Response
Office of Compliance
CDER | US FDA

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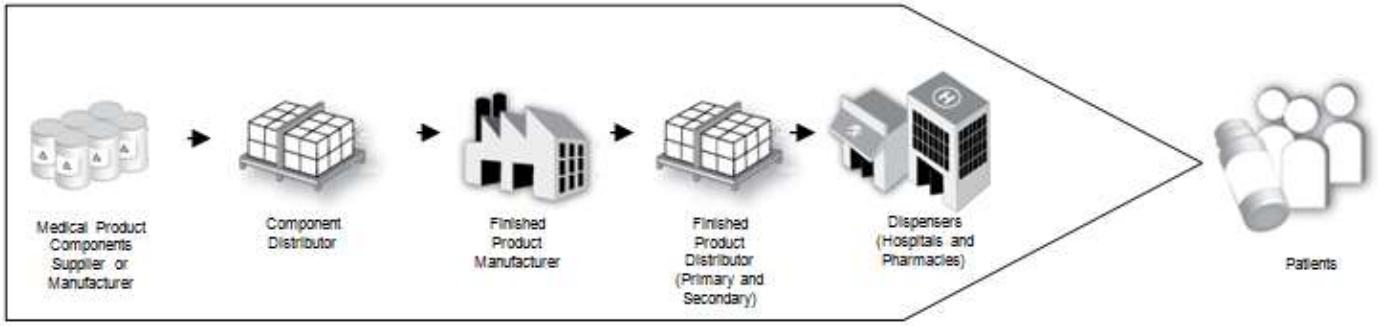
Learning Objectives

- Provide an overview of key supply chain security requirements under the Drug Supply Chain Security Act (DSCSA) for the distribution of prescription drugs
- Describe implementation updates for trading partners in the pharmaceutical supply chain (manufacturers, repackagers, wholesale distributors and dispensers)

Pharmaceutical Supply Chain



Maintaining integrity from manufacturer to patient(s)

- Who touches the product?
- Where are the vulnerabilities?
- What are the threats?

Protect the product → **Protect the patient**

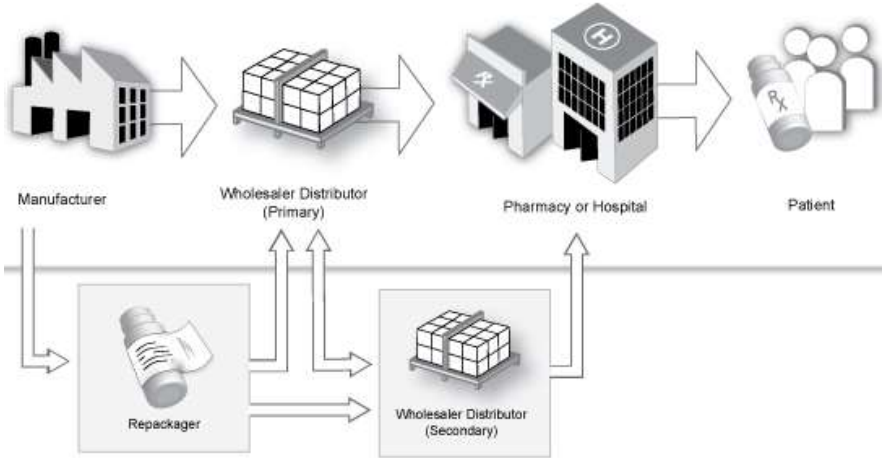
Threats to the Pharmaceutical Supply Chain

Illegitimate product

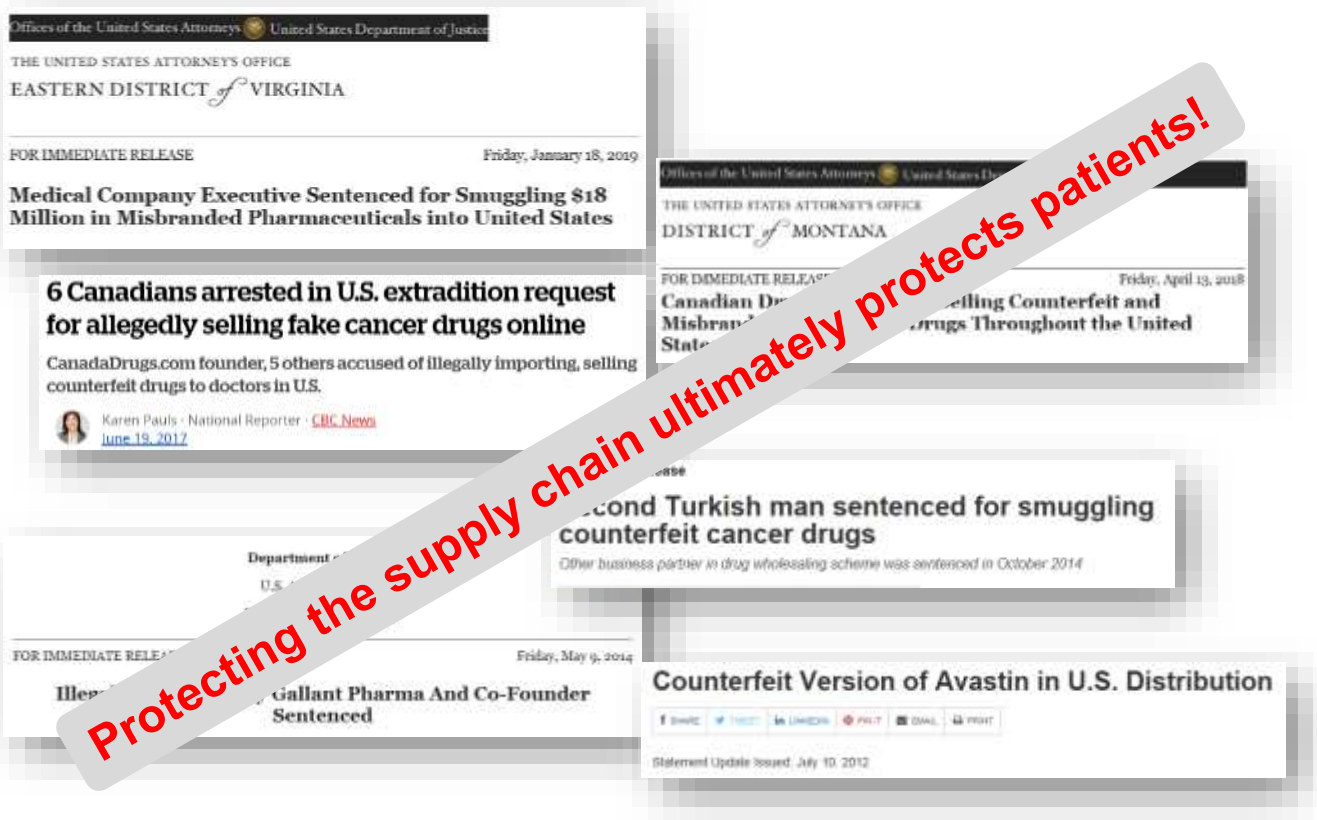
Counterfeit, diverted, stolen, intentionally adulterated, subject to a fraudulent transaction, or otherwise unfit for distribution that would result in serious adverse health consequences or death to humans

Unscrupulous players

- Distribute illegitimate product
- Don't maintain quality of the product
- Don't maintain security or integrity of the supply chain (examples: are not authorized or do business with entities that are not authorized)



Weakness in the drug supply chain can be anywhere


Offices of the United States Attorneys
United States Department of Justice
THE UNITED STATES ATTORNEY'S OFFICE
EASTERN DISTRICT of VIRGINIA
FOR IMMEDIATE RELEASE
Friday, January 18, 2019
Medical Company Executive Sentenced for Smuggling $18 Million in Misbranded Pharmaceuticals into United States
6 Canadians arrested in U.S. extradition request for allegedly selling fake cancer drugs online
CanadaDrugs.com founder, 5 others accused of illegally importing, selling counterfeit drugs to doctors in U.S.
Karen Pauls · National Reporter · CBC News
June 19, 2017
THE UNITED STATES ATTORNEY'S OFFICE
DISTRICT of MONTANA
Friday, April 13, 2018
cond Turkish man sentenced for smuggling counterfeit cancer drugs
Other business partner in drug wholesaling scheme was sentenced in October 2014
Friday, May 9, 2014
Gallant Pharma And Co-Founder Sentenced
Counterfeit Version of Avastin in U.S. Distribution
Statement Update Issued: July 10, 2012
Protecting the supply chain ultimately protects patients!

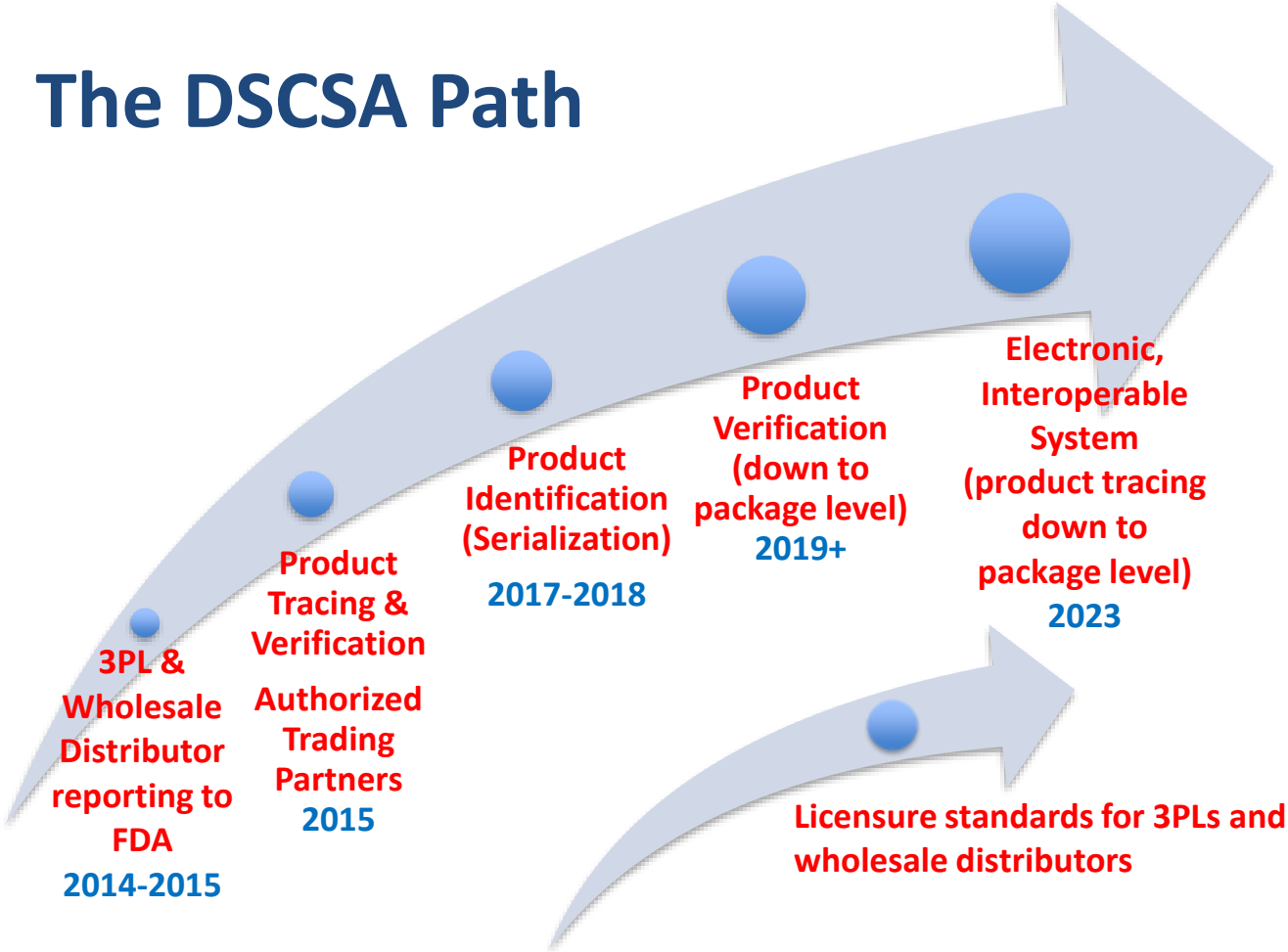
DSCSA Goals

1. Implement an interoperable, electronic tracing of products at the package level by 2023 that will:

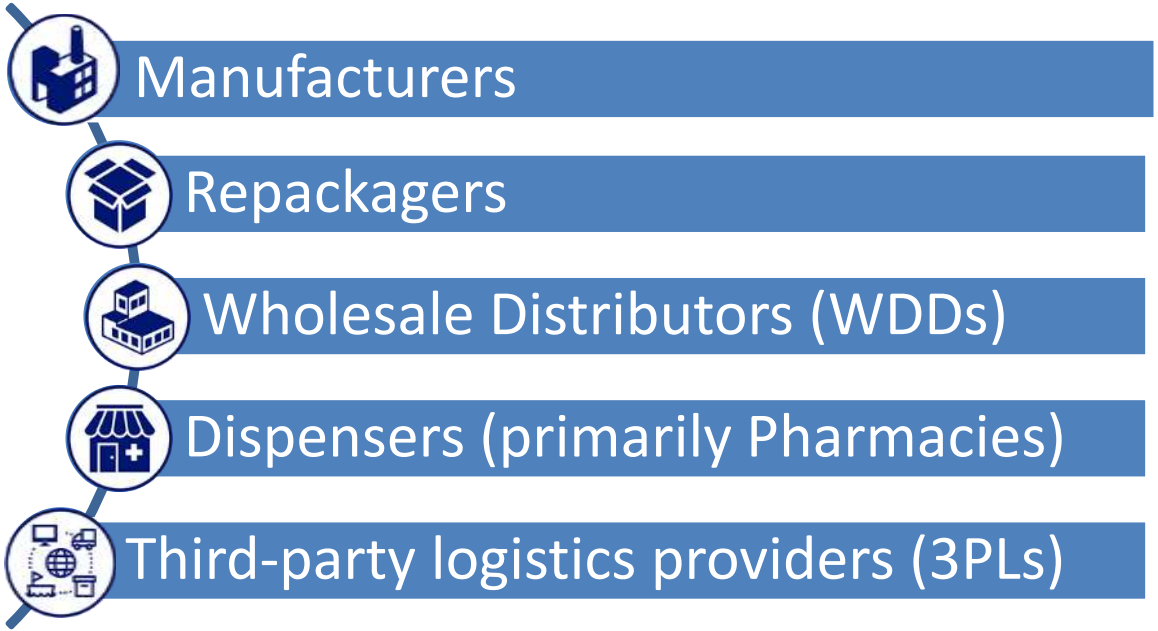
- Enable secure tracing of product at the package level
- Use product identifiers to verify product at the package level
- Enable prompt response to suspect and illegitimate products when found
- Improve efficiency of recalls

2. Establish national standards for licensure for wholesale distributors and third-party logistics providers (3PLs)

The DSCSA Path



Trading Partners under DSCSA



Products

- 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

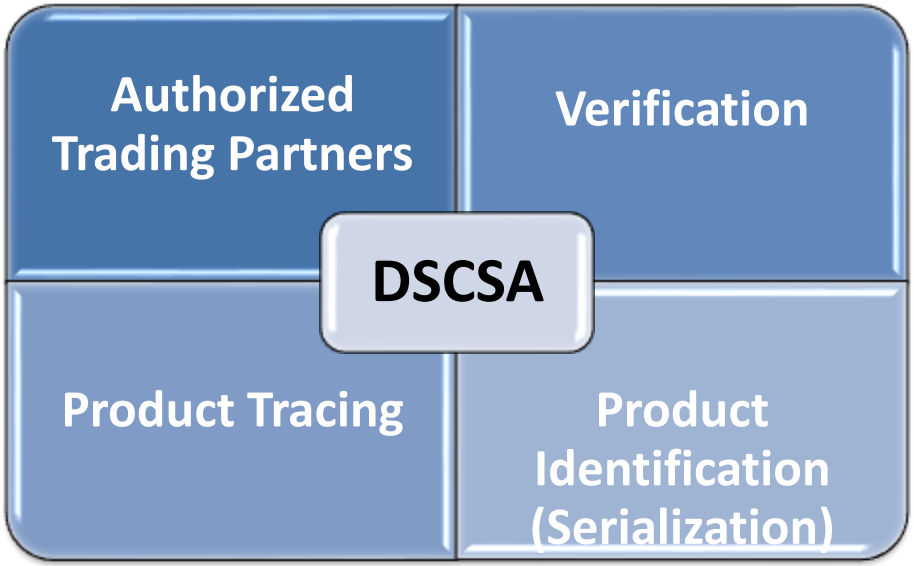
Refer to the definition for "product" in section 581(13) of the FD&C Act for specific information regarding exceptions.

Transactions

- Involve transfers of product where a *change of ownership* occurs
- Excludes:
  - Intracompany 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
  - Certain activities by charitable organizations
  - Distributions pursuant to a merger or sale
  - Certain combination products
  - Certain medical kits
  - Certain IV products
  - Medical gas distribution
  - Approved animal drugs

Refer to the definition for "transaction" in section 581(24) of the FD&C Act for specific information regarding exclusions.

Key Requirements*



*The requirements under section 582 of the FD&C Act apply to manufacturers, repackagers, wholesale distributors, and dispensers (pharmacies).

Trading Partners must be *Authorized*

Manufacturers and Repackagers	WDDs and 3PLs	Dispensers (Pharmacies)
• Have valid registration with FDA • Check FDA's drug establishment current registration site database (DECRS)	• Have valid State or Federal license and compliance with reporting requirements • Check FDA's WDD/3PL database	• Have valid State license • Check respective state authorities

Guidance: Authorized Trading Partners

Identifying Trading Partners under DSCSA

Assists industry and State and local governments in understanding the applicability of DSCSA requirements to entities in the drug supply chain and activities that require licensure and annual reporting, as well as other requirements related to being an authorized trading partner

Specific clarifications -

- Manufacturers: Manufacturing establishments, application holders, co-licensed partners, affiliates
- Repackagers: Does not include a pharmacy solely engaged in packaging/labeling for an identified patient after receipt of a valid Rx
- Wholesale Distributors: Differences in the definition of wholesale distribution in the Prescription Drug Marketing Act (PDMA) and DSCSA, some entities are now 3PLs
- 3PLs: What is considered as “other logistic services” and brokers, solution providers, common carriers are generally not considered as 3PLs
- Dispensers: No product tracing requirements if product is dispensed to a patient or if it is a dispenser to dispenser sale to fulfill a specific patient need

Challenge Question #1

Who is considered a “trading partner” and must comply with supply chain security requirements under DSCSA?

A. Manufacturers

B. Repackagers

C. Wholesale Distributors

D. Dispensers

E. All of the above

Product Tracing Requirement

Receive	When buying, only accept prescription drugs with product tracing information: (1) Transaction Information (TI) (2) Transaction History (TH) (3) Transaction Statement (TS)
Provide	Generate and provide product tracing information with each transaction if you sell a prescription drug to another trading partner.
Respond	Respond to a request for information in the event of a recall or to investigate a suspect or illegitimate product.
Store	Store product tracing information you receive in paper or electronic format for at least 6 years.
Return	Return product to the trading partner that you bought the drug from.

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CURRENTLY LOT-LEVEL AND IN PAPER OR ELECTRONIC FORMATS

IN 2023, CHANGES TO PACKAGE-LEVEL TRACING AND ALL ELECTRONIC

Guidances: Standards for Product Tracing

DSCSA Standards for the Interoperable Exchange of Information for Product Tracing…

- Can use or build on current systems and processes to comply with requirements
- Can be paper- or electronic-based until 2023 when it will be required to be electronic
- Provides examples of methods that could be used for data exchange

Standardization of Data and Documentation Practices for Product Tracing

- Recommends how to standardize the data contained in product tracing information (TI, TH, TS)
- Describes data elements that should be including in product tracing information, including situations where it is permitted by law for certain data to be omitted
  - Dispenser to dispenser sales to fulfill a specific patient need
  - Drop shipments to a dispenser
  - Grandfathered product
- Clarifies the use of third-party agreements

Investigate and properly handle suspect and illegitimate products

Suspect Product: ***reason to believe*** that product potentially is:

- counterfeit, diverted, stolen
- subject of fraudulent transaction
- intentionally adulterated or appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans

Illegitimate Product: ***credible evidence*** shows that the product is:

- counterfeit, diverted, stolen
- subject of fraudulent transaction
- intentionally adulterated or appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans

Identifying suspect product: Examples of what to look for…

Verification Requirements

Quarantine and Investigate	Suspect prescription drugs to determine if illegitimate
Investigation	- Must include validating applicable transaction information and transaction history - Once product is serialized, trading partners will need to verify lot number and product identifier
Notify	If the product is illegitimate, notify FDA and certain immediate trading partners within 24 hours
Respond	If the product is illegitimate, work with manufacturer to take steps to prevent it from reaching patients
Store	Store records of investigation of suspect product and the disposition of illegitimate product for at least 6 years

Guidances: Verification Requirements

DSCSA Implementation: Identification of Suspect Product and Notification

Describes scenarios that increase risk of suspect product entering the supply chain:

- recommendations on how to identify and make determination of suspect product
- process to notify FDA and terminate notifications about illegitimate product (Form FDA 3911)

Definitions of Suspect Product and Illegitimate Product for Verification Requirements under DSCSA

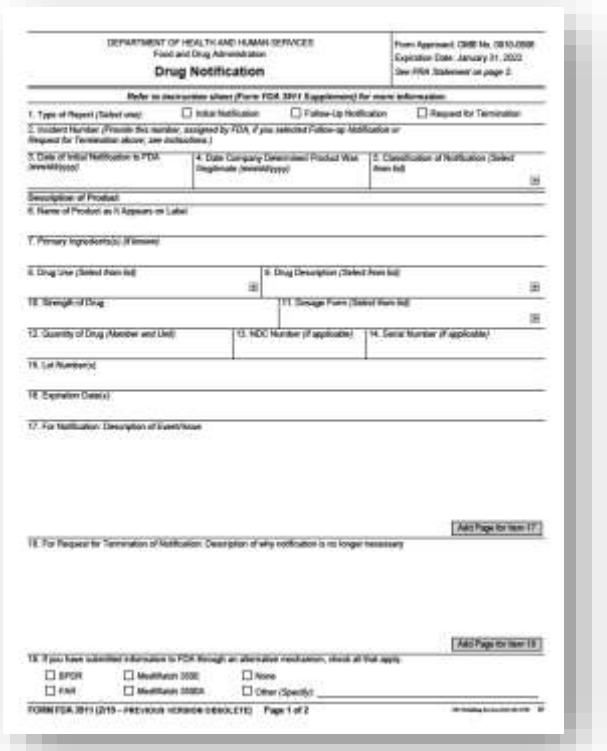
Clarifies FDA interpretations of terms with in the definitions:

- counterfeit, diverted, subject of fraudulent transaction, unfit for distributions
- aids in determining when to report an illegitimate product to FDA

Verification Systems under DSCSA…

- Provides recommendations for robust verification system for the determination, quarantine, and investigation of suspect products, and quarantine, notification, and disposition of illegitimate products
- Describes recommendations for how trading partners submit cleared product notifications and respond to verifications requests
- Addresses verification of saleable returns at the package level for product identifiers on packages and homogenous cases

Notify FDA if you have Illegitimate Product



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Drug Notification

Notify FDA within 24 hours using Form FDA 3911

Notify other trading partners within 24 hours

Request notification termination using Form FDA 3911

https://www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm

Product identifier Requirements (Serialization)

Manufacturers/Repackagers (November 2018)

- Encode product identifiers on prescription drug packages
- Determine smallest individual saleable unit
- Verification requirements changes once products are serialized with product identifier

Product Identifier

- National Drug Code (NDC)
- Serial Number
- Lot Number
- Expiration Date

Human and machine readable formats

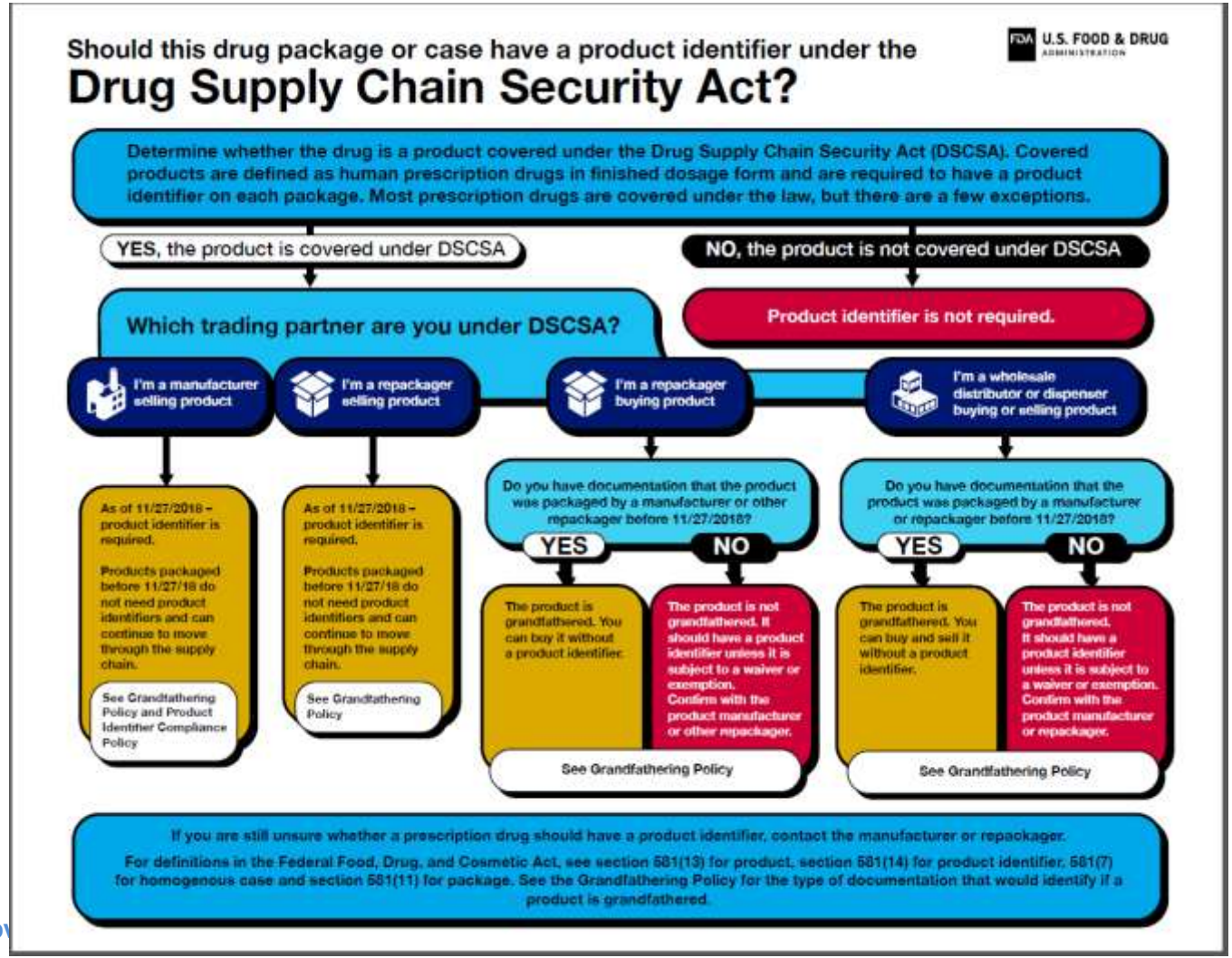
Machine readable barcodes:

- 2D data matrix for packages
- Linear or 2D data matrix for homogenous cases

Packages Without Product Identifiers

Excluded Products	Not all prescription drugs are required to have a product identifier and are excluded.
Grandfathered	Some products will be in the supply chain before the product identifier requirement took effect.
Waiver, Exception or Exemption	Some products were granted a waiver, exception or exemption from the product identifier requirement.

If you are unsure whether a product should have a product identifier, verify with the manufacturer or repackager.


Should this drug package or case have a product identifier under the
Drug Supply Chain Security Act?
U.S. FOOD & DRUG ADMINISTRATION
Determine whether the drug is a product covered under the Drug Supply Chain Security Act (DSCSA). Covered products are defined as human prescription drugs in finished dosage form and are required to have a product identifier on each package. Most prescription drugs are covered under the law, but there are a few exceptions.
YES, the product is covered under DSCSA
NO, the product is not covered under DSCSA
Product identifier is not required.
Which trading partner are you under DSCSA?
I'm a manufacturer selling product
I'm a repackager selling product
I'm a repackager buying product
I'm a wholesale distributor or dispenser buying or selling product
As of 11/27/2018 – product identifier is required.
Products packaged before 11/27/18 do not need product identifiers and can continue to move through the supply chain.
See Grandfathering Policy and Product Identifier Compliance Policy
As of 11/27/2018 – product identifier is required.
Products packaged before 11/27/18 do not need product identifiers and can continue to move through the supply chain.
See Grandfathering Policy
Do you have documentation that the product was packaged by a manufacturer or other repackager before 11/27/2018?
YES
NO
The product is grandfathered. You can buy it without a product identifier.
The product is not grandfathered. It should have a product identifier unless it is subject to a waiver or exemption. Confirm with the product manufacturer or other repackager.
See Grandfathering Policy
Do you have documentation that the product was packaged by a manufacturer or repackager before 11/27/2018?
YES
NO
The product is grandfathered. You can buy and sell it without a product identifier.
The product is not grandfathered. It should have a product identifier unless it is subject to a waiver or exemption. Confirm with the product manufacturer or repackager.
See Grandfathering Policy
If you are still unsure whether a prescription drug should have a product identifier, contact the manufacturer or repackager.
For definitions in the Federal Food, Drug, and Cosmetic Act, see section 581(13) for product, section 581(14) for product identifier, 581(7) for homogenous case and section 581(11) for package. See the Grandfathering Policy for the type of documentation that would identify if a product is grandfathered.

Guidance: Product Identifier Requirements

Product Identifiers under DSCSA, Questions and Answers

- Provides FDA contacts for barcode-related questions
- Describes recommendations for standardizing both the human-readable and machine-readable format of the information that is contained in the product identifier
- Describes submission of label changes under DSCSA
- Clarifies FDA's interpretation of product identifier requirements under DSCSA as they relate to linear barcode requirements under 21 CFR 201.25
- Provides examples of when the product identifier and/or the linear barcode are required on product packages

Challenge Question #2

Which of the following statements is NOT true about DSCSA requirements?

A. Product tracing involves providing the transaction information, transaction history and transaction statement with each sale of product.

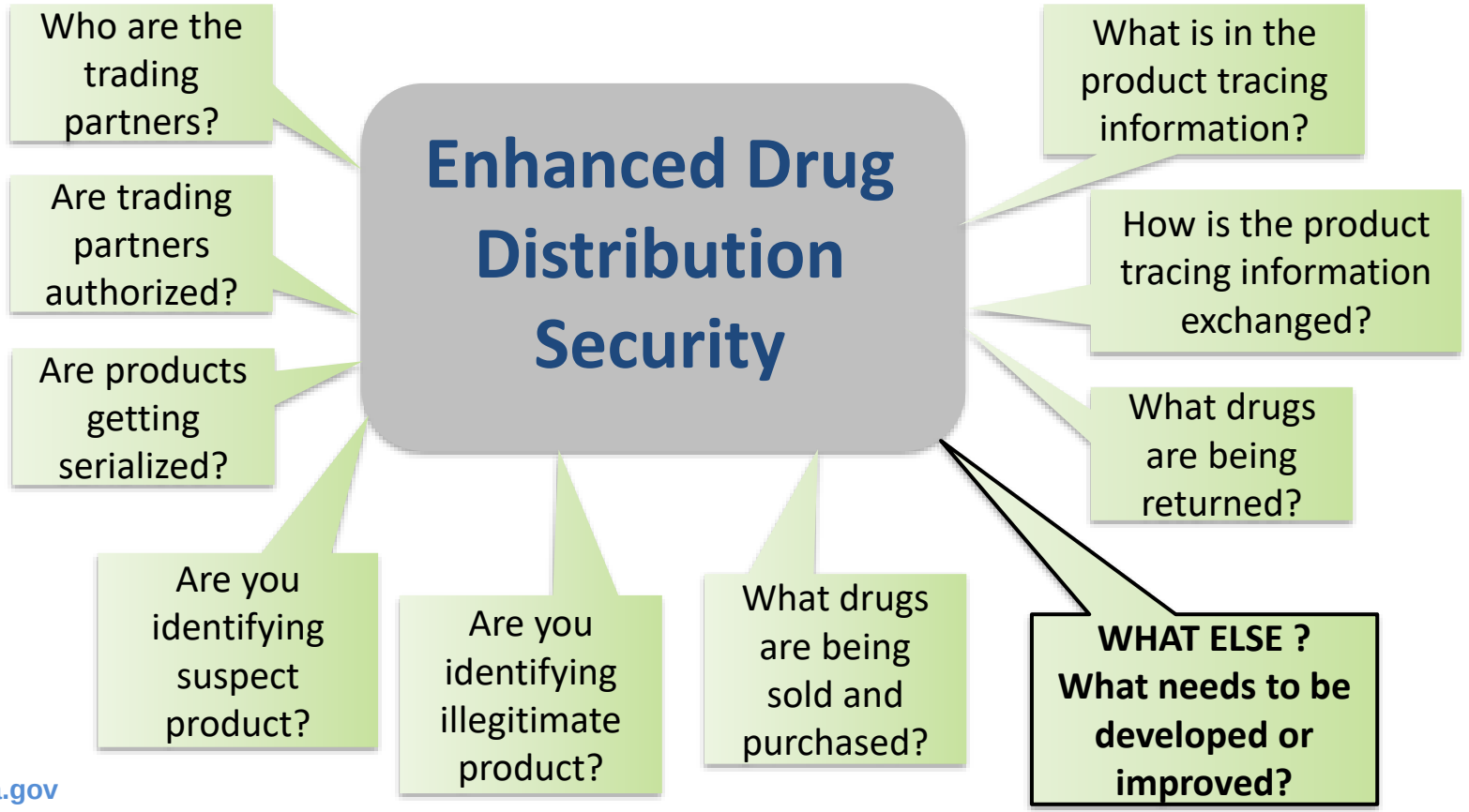
B. Verification includes quarantine and investigation of suspect product and quarantine and disposition of illegitimate product.

C. When a trading partner identifies illegitimate product, it must notify FDA and other immediate trading partners within 1 week of making the determination.

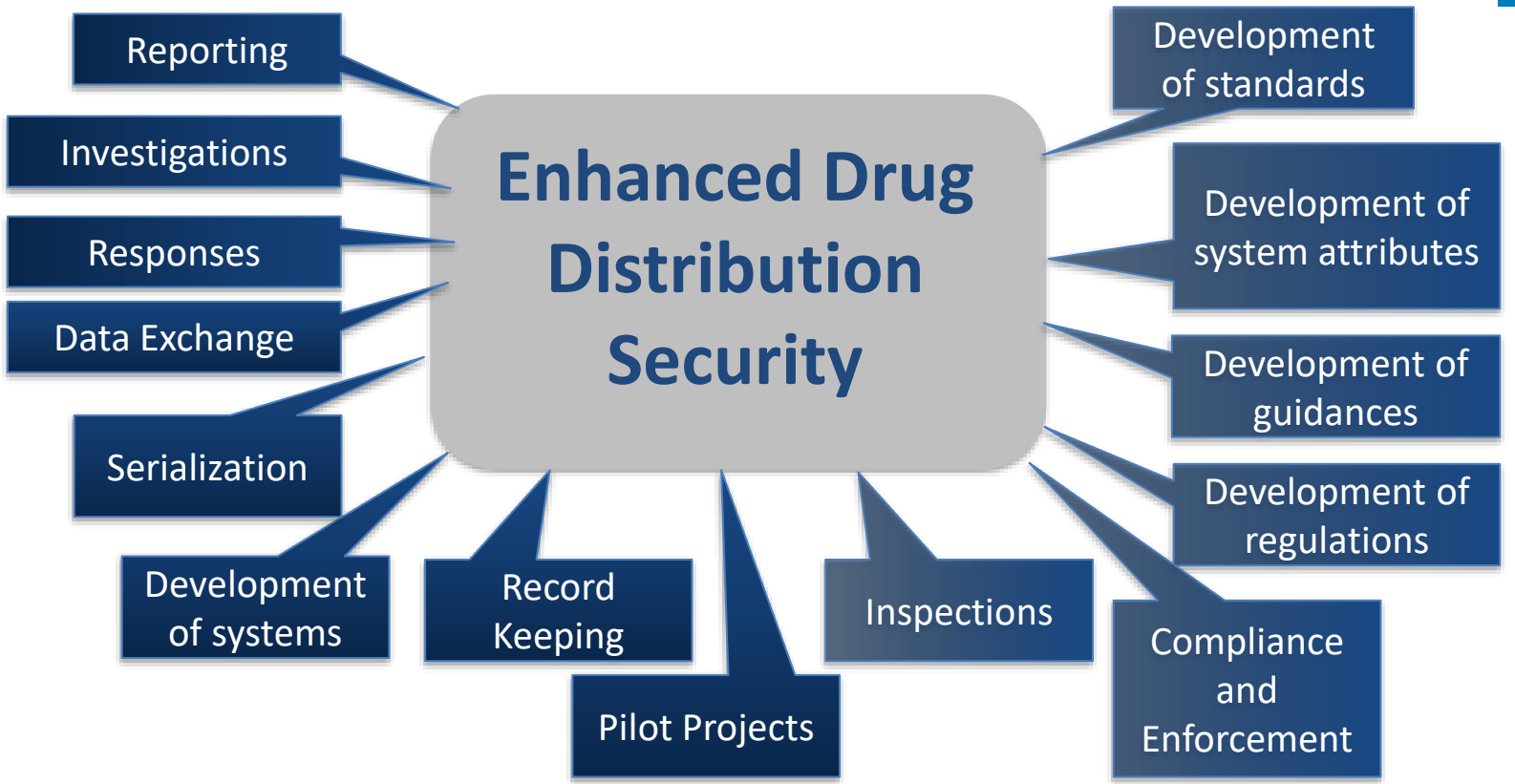
D. Trading partners can notify FDA of illegitimate product using the Form FDA 3911 for Drug Notifications.

E. Product identifiers encoded on product packages in a 2D data matrix barcode include the NDC, serial number, lot number and expiration date.

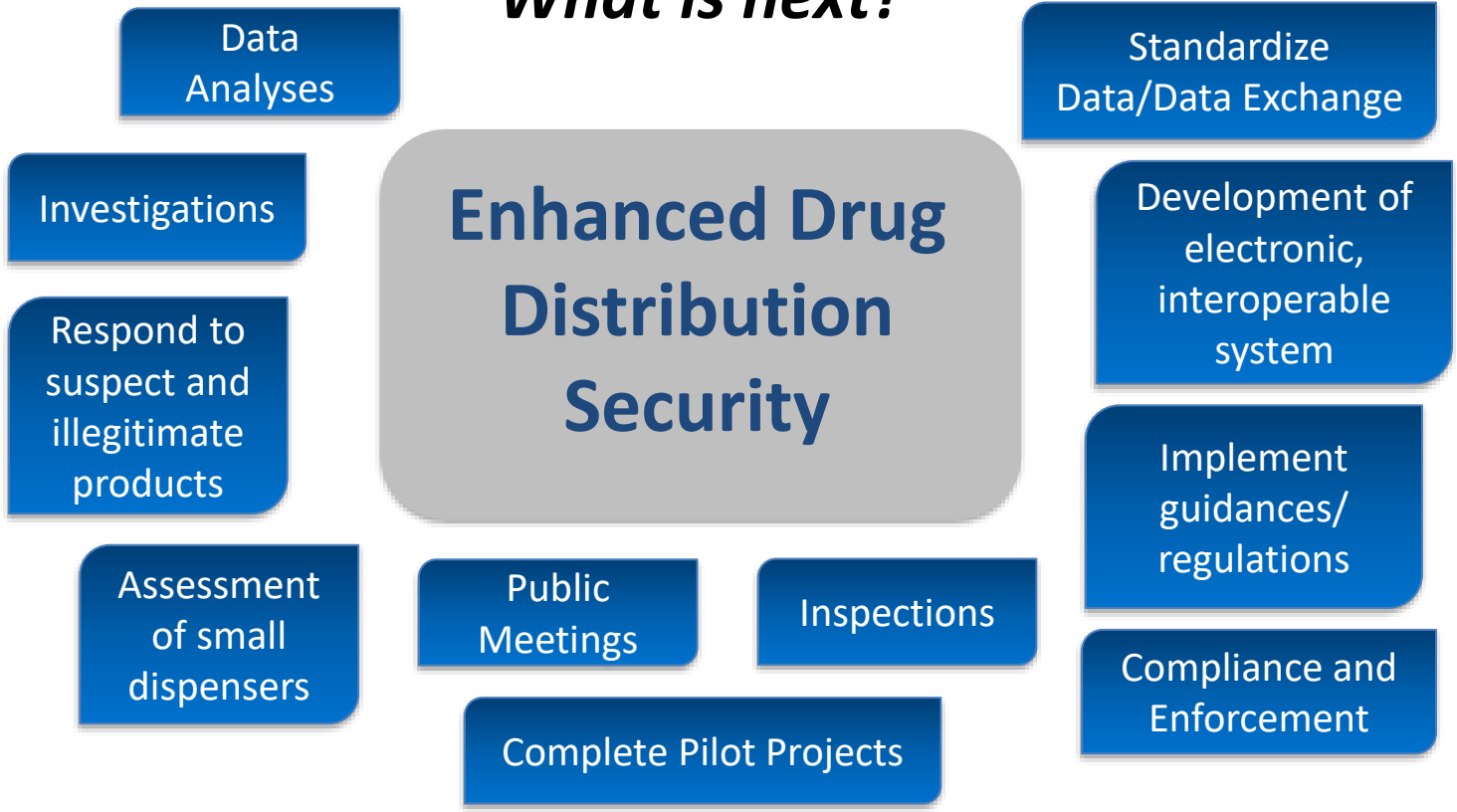
Are we there yet?



Current and future efforts



What is next?


Data Analyses
Standardize Data/Data Exchange
Investigations
Enhanced Drug Distribution Security
Development of electronic, interoperable system
Respond to suspect and illegitimate products
Implement guidances/ regulations
Assessment of small dispensers
Public Meetings
Inspections
Compliance and Enforcement
Complete Pilot Projects

FDA Resources

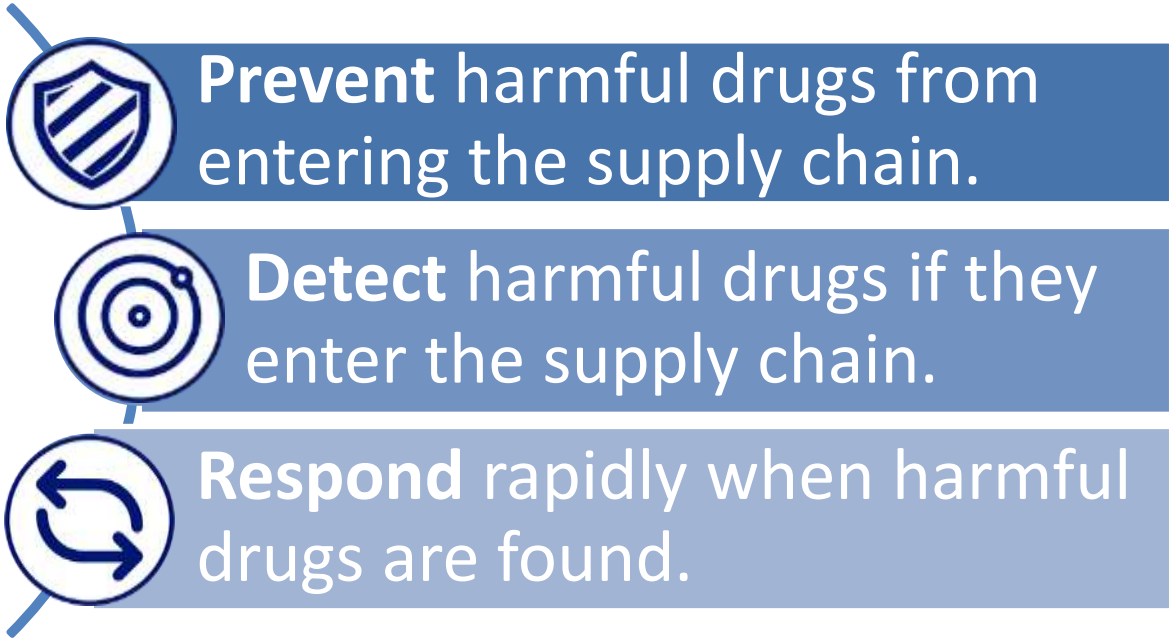
- DSCSA main webpage

  https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm

- DSCSA regulatory documents (i.e., regulations, guidances, federal register notices, pilot programs)

  https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm424963.htm

How DSCSA Protects Patients



Questions?

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