U.S. FOOD & DRUG ADMINISTRATION

# U.S. Requirement for Traceability of Drugs: The Drug Supply Chain Security Act (DSCSA)


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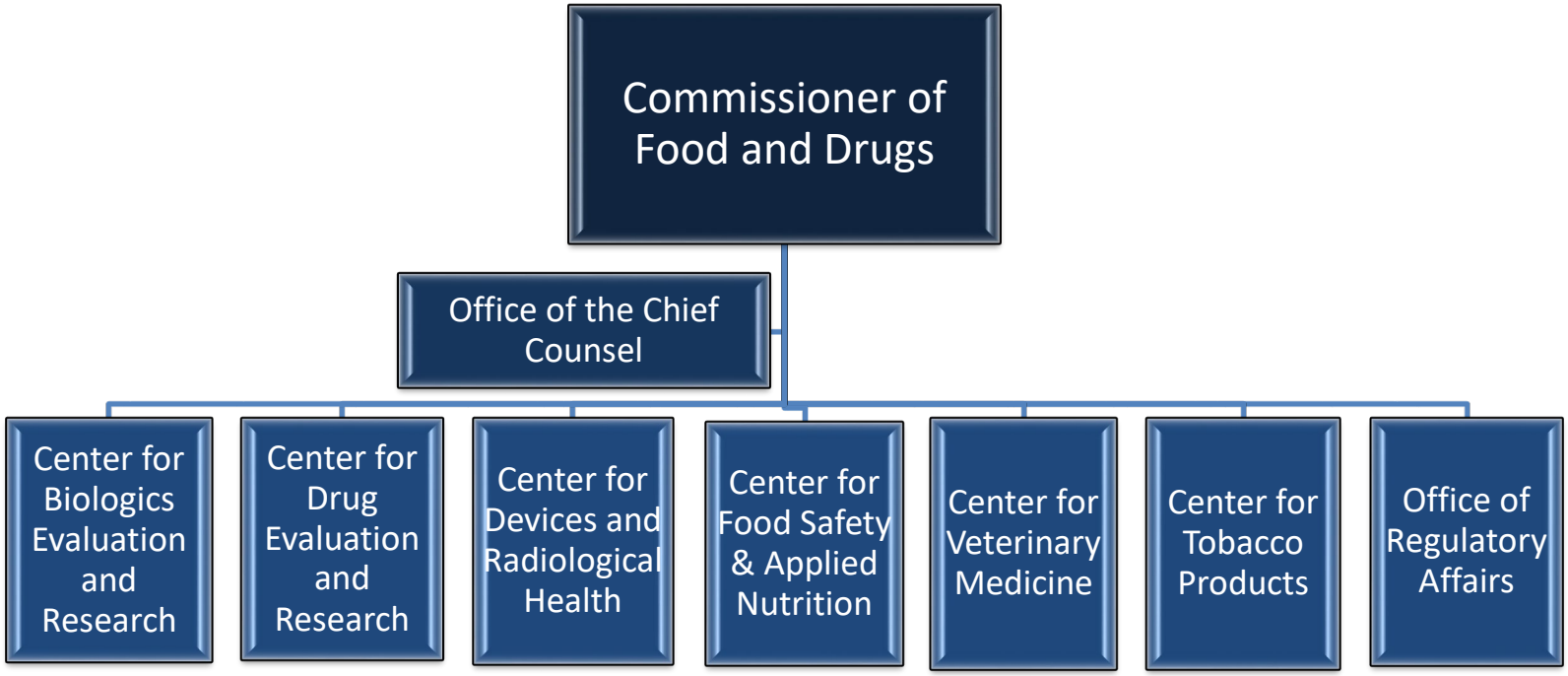
# Disclaimer

**The content here is intended only to provide a summary and general overview. It is not intended to be comprehensive nor does it constitute legal advice.**

# Additional Resources

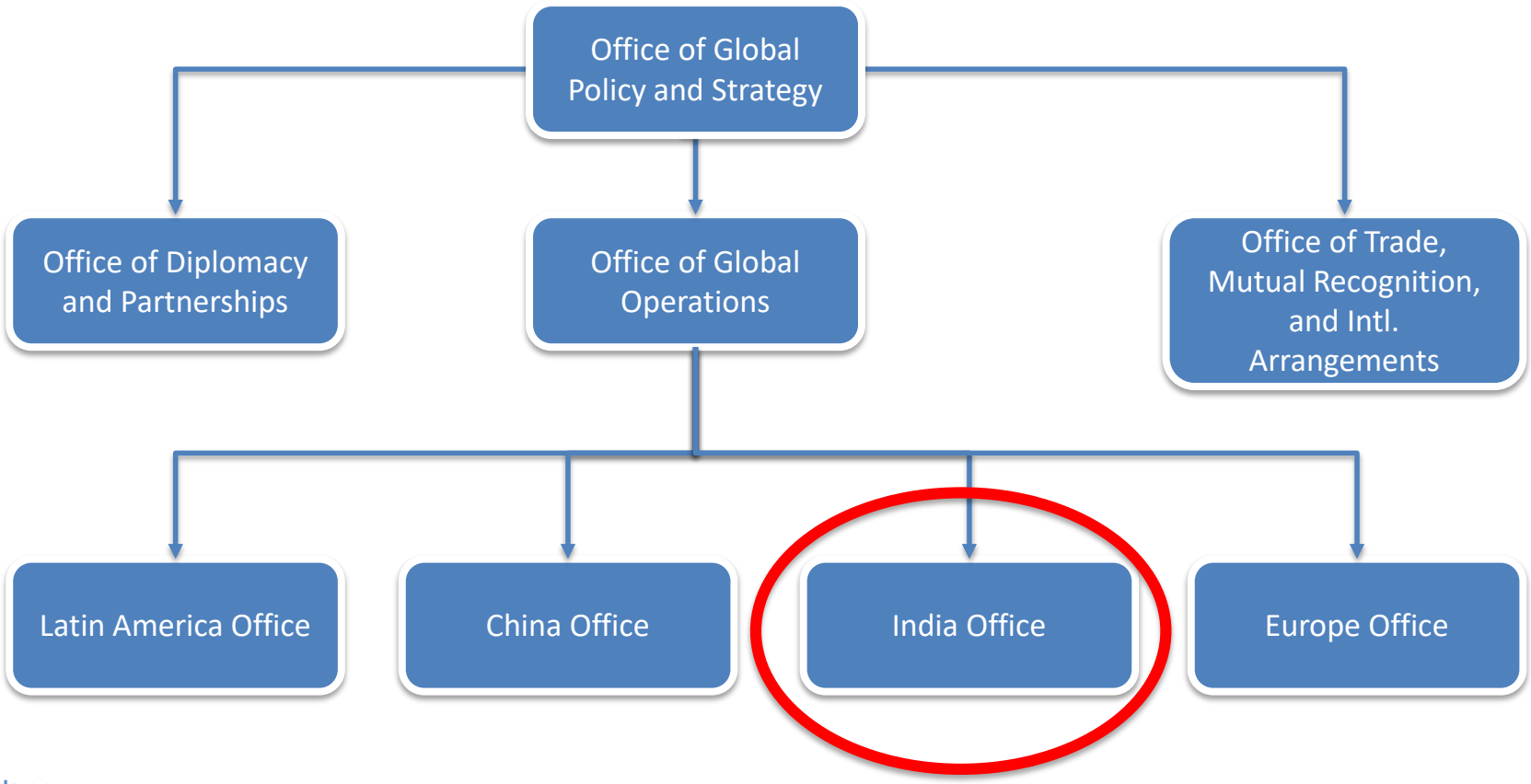
**Updates and links to FDA documents or notices summarized in this presentation can be found on the DSCSA webpage on FDA's website.**

FDA U.S. FOOD & DRUG ADMINISTRATION




(Simplified organizational representation)

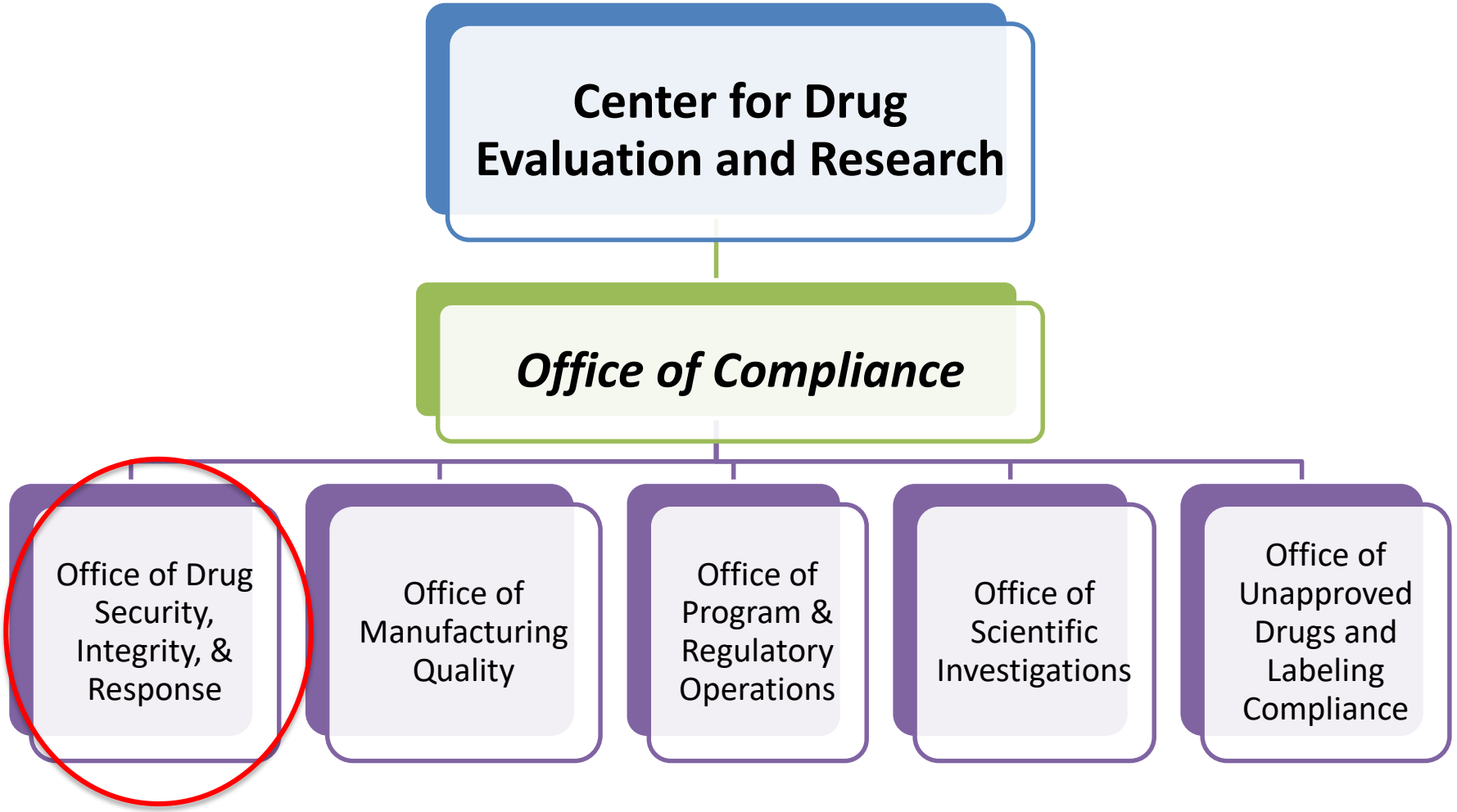
# Office of Global Policy and Strategy



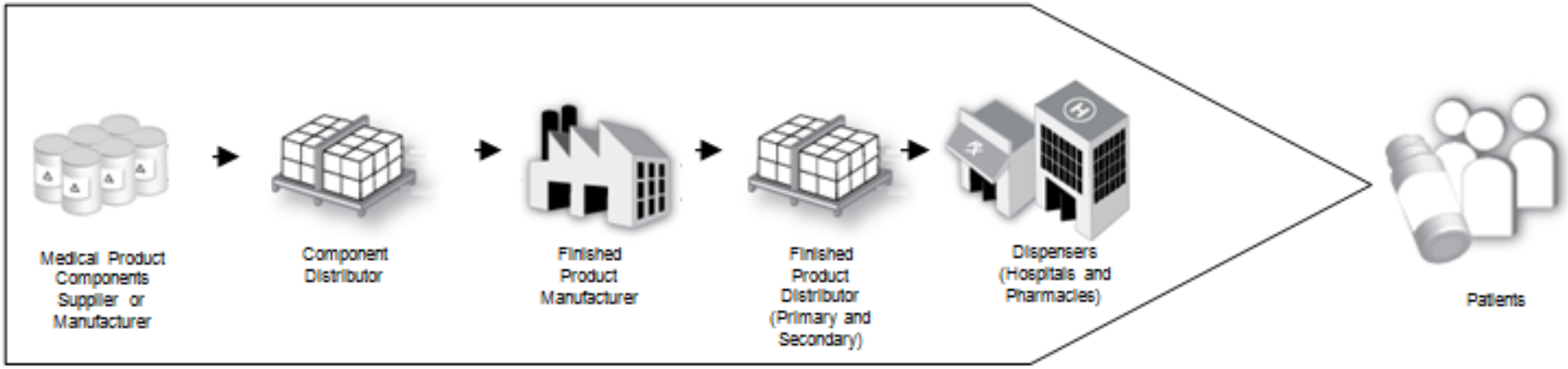
# Office of Global Policy and Strategy

**OGPS MISSION STATEMENT**: OGPS works to protect and enhance the public health of Americans by ensuring that global considerations are fully integrated into the Agency's policies and operational activities.

# CDER's Office of Compliance



# Pharmaceutical Supply Chain

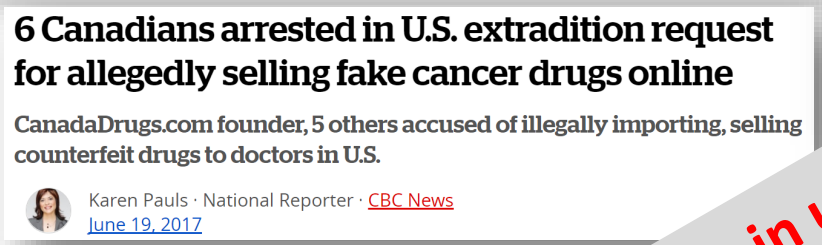


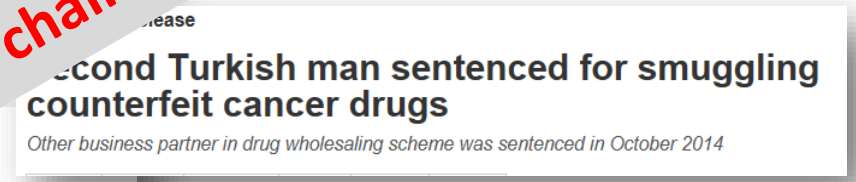

Maintaining integrity from manufacturer to patient(s)

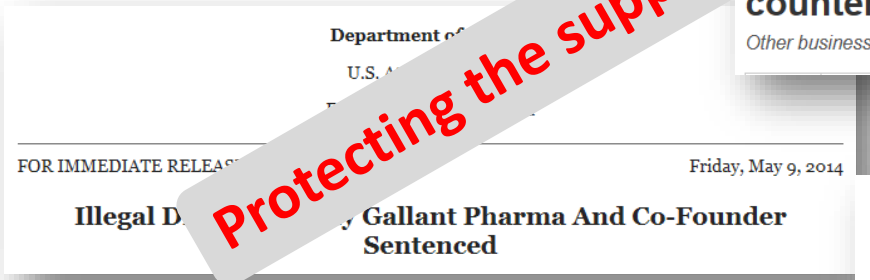
- Who touches the product?
- Where are the vulnerabilities?
- What are the threats?

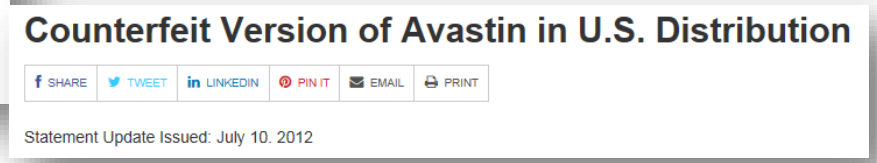
**Protect the product** → **Protect the patient**






Protecting the supply chain ultimately protects patients!

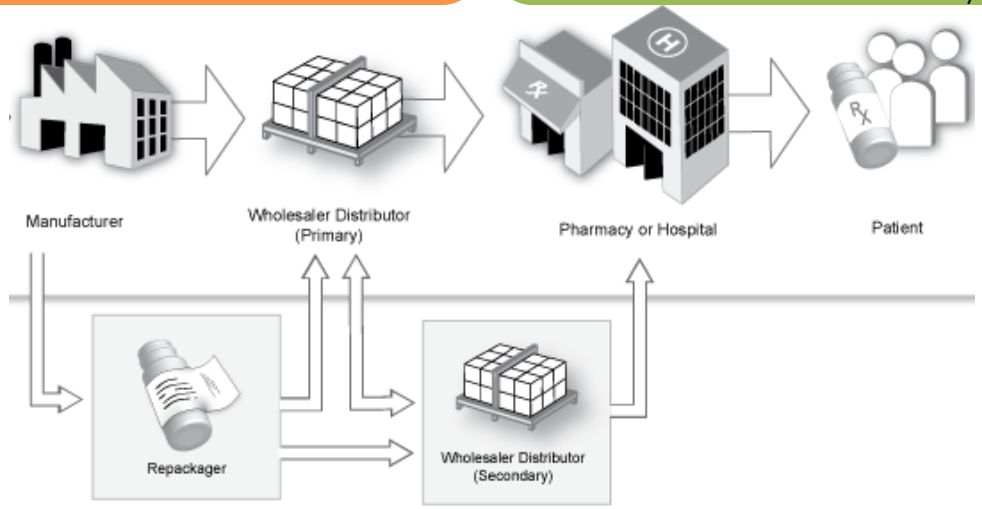
# Threats to the Pharmaceutical Supply Chain

**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**

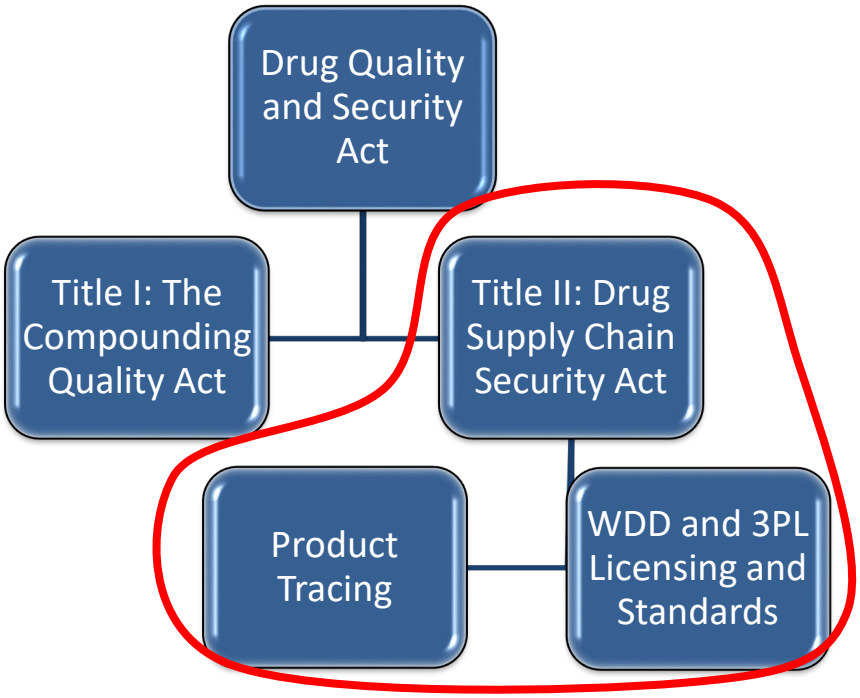
- Distribute illegitimate product
- Don't maintain quality of the product
- Don't maintain security or integrity of the supply chain (examples: are not authorized or do business with entities that are not authorized)




***Weakness in the drug supply chain can be anywhere***

# Overview of the DSCSA

Drug Supply Chain Security Act (DSCSA) adds new sections in the Federal Food, Drug and Cosmetic Act (FD&C Act):




- 581 – Definitions
- 582 – Requirements (product tracing, product identification, verification)
- 583 – Standards for licensure of wholesale distributors (WDD)
- 584 – Standards for licensure of third-party logistics providers (3PLs)
- 585 – Uniform national policy

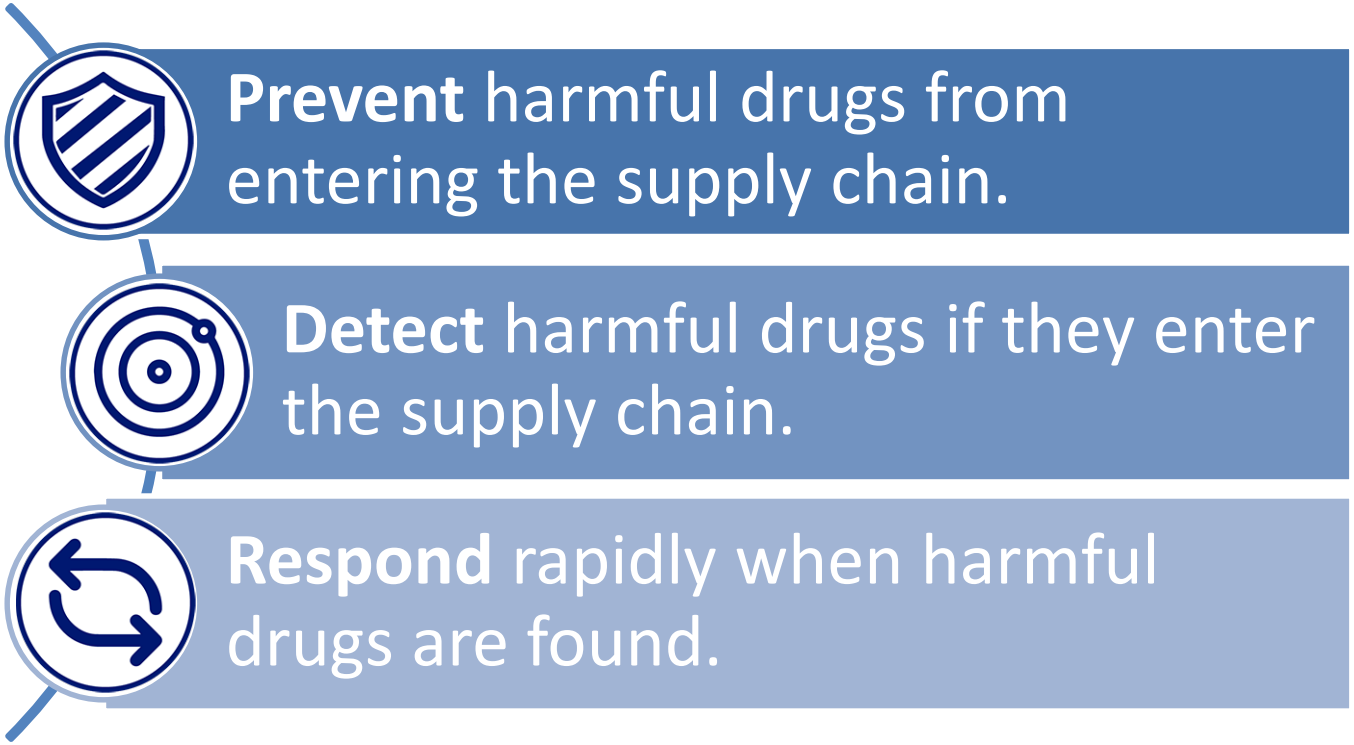
# DSCSA Goals

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

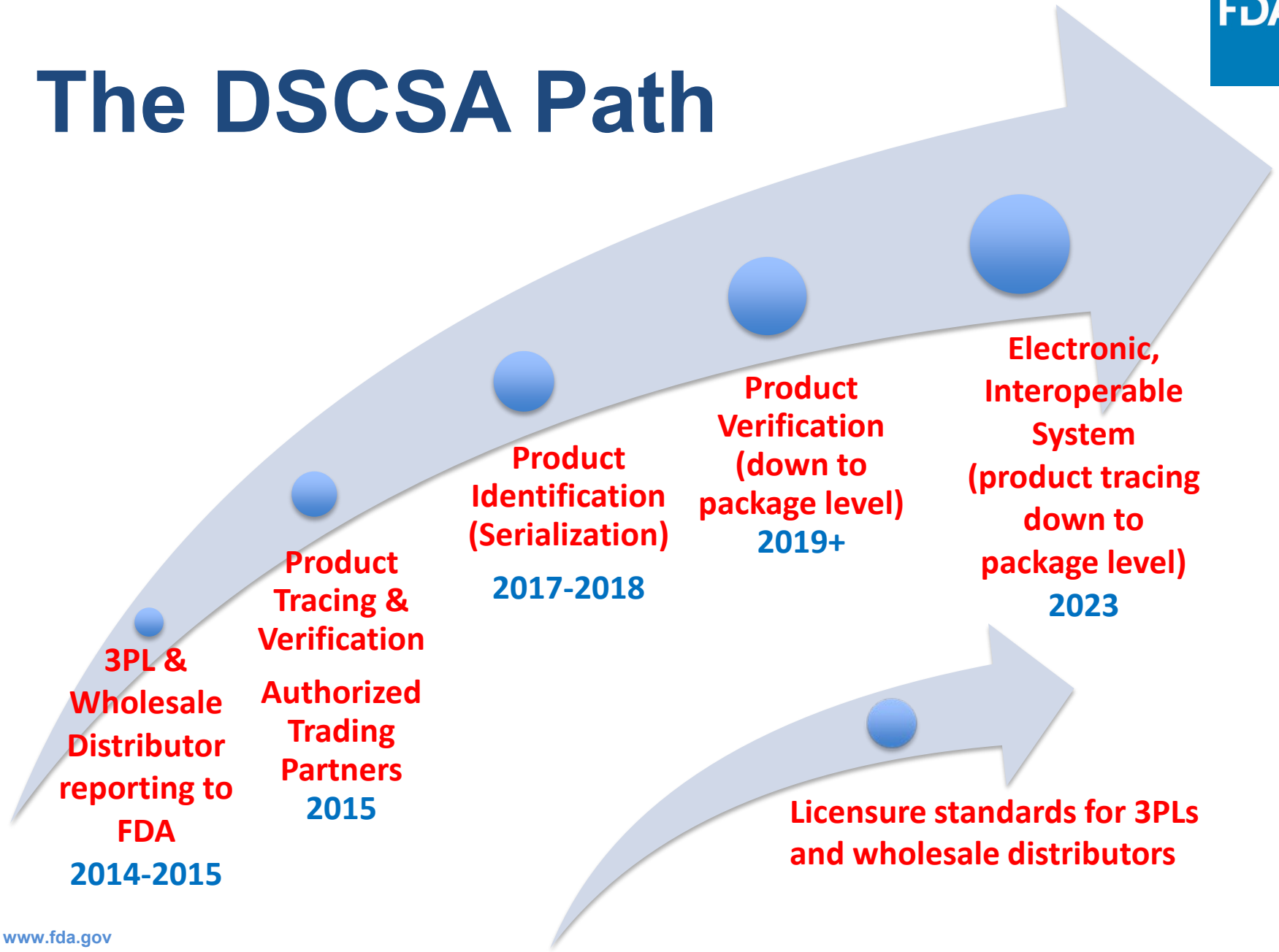
- Enable secure tracing of product at the package level
- Use product identifiers to verify product at the package level
- Enable prompt response to suspect and illegitimate products when found
- Improve efficiency of recalls

2. Establish national standards for licensure for wholesale distributors and third-party logistics providers

# How DSCSA protects patients



# The DSCSA Path



# 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

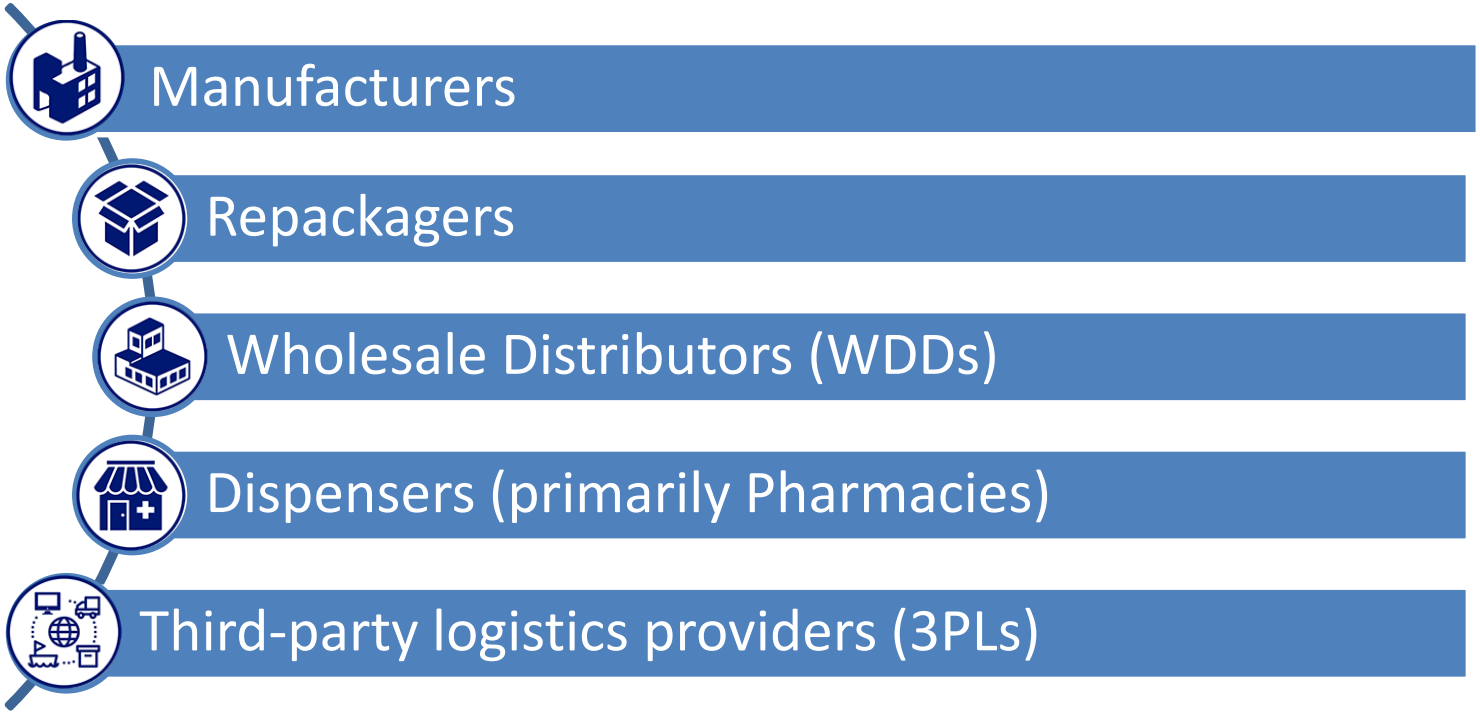
*Refer to the definition for "product" in section 581(13) of the FD&C Act for specific information regarding exceptions.*

# Transactions

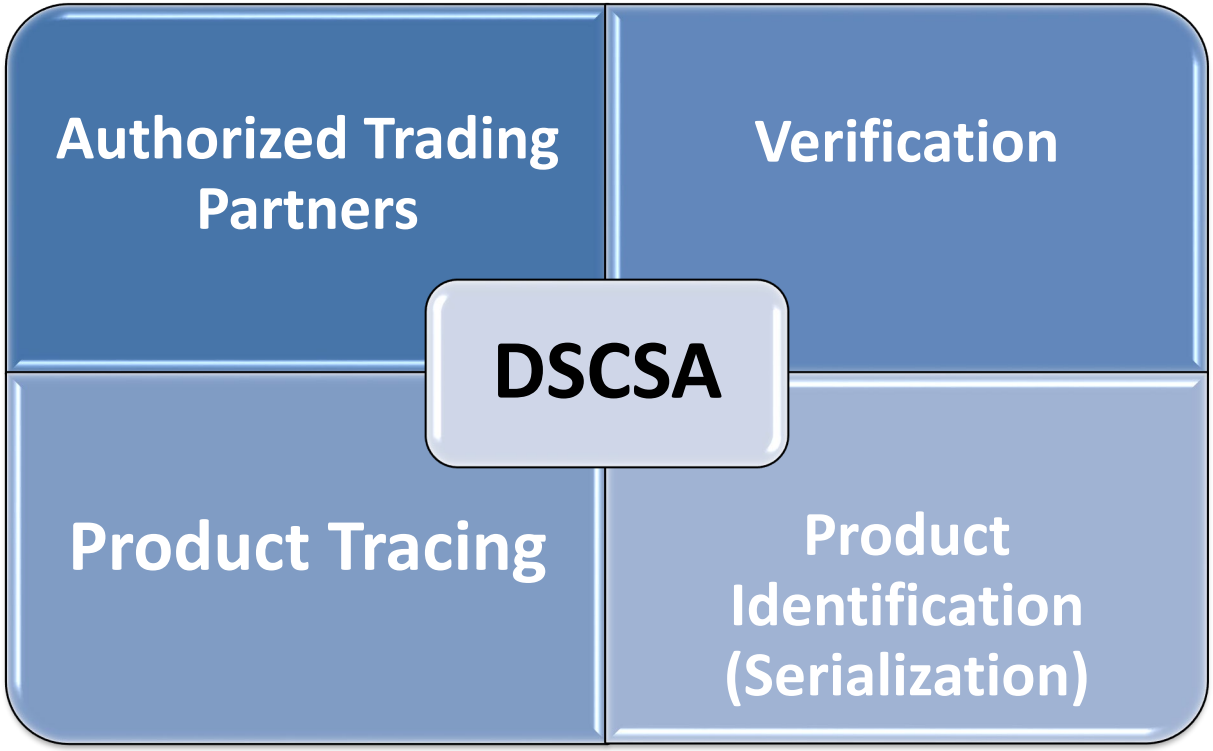
- Involve transfers of product where a *change of ownership* occurs
- Excludes:
  - Intracompany distributions
  - Distribution among hospitals under common control
  - Public health emergencies
  - Dispensed pursuant to a prescription
  - Product sample distribution
  - Blood and blood components for 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.*

# Trading Partners under DSCSA



# Key Requirements*




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

# Authorized Trading Partner Requirement

## Manufacturers and Repackagers

- Have valid registration with FDA
- Check FDA's drug establishment current registration site database (DECRS)

## Wholesale Distributors and 3PLs

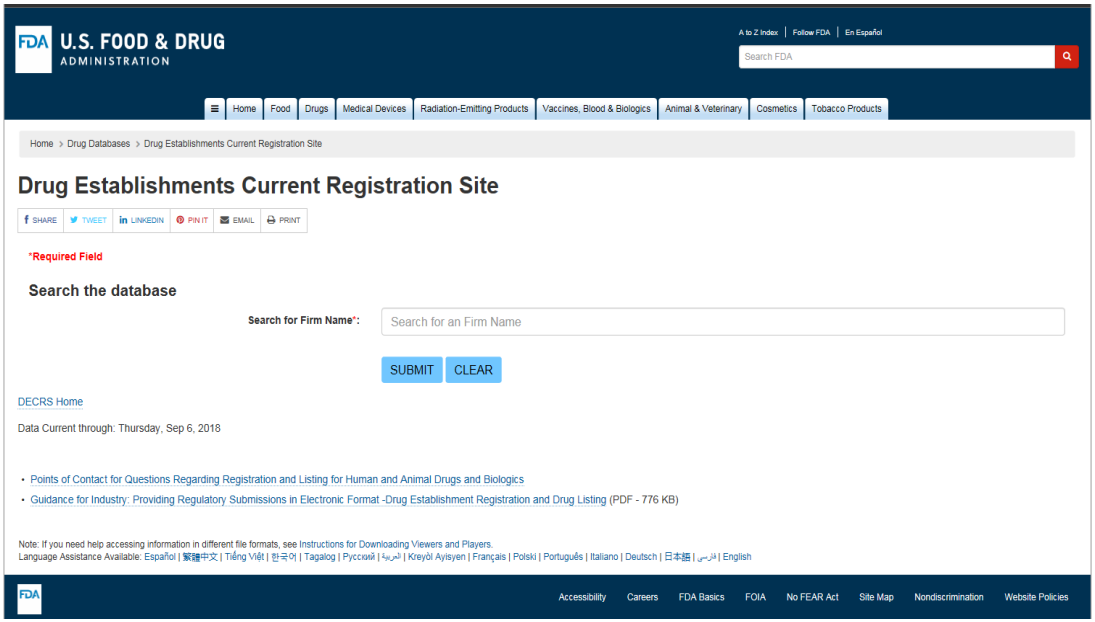
- Have valid State or Federal license and compliance with reporting requirements
- Check FDA's WDD/3PL database

## Dispensers

- Have valid State license
- Check respective state authorities

Trading partners must be authorized!

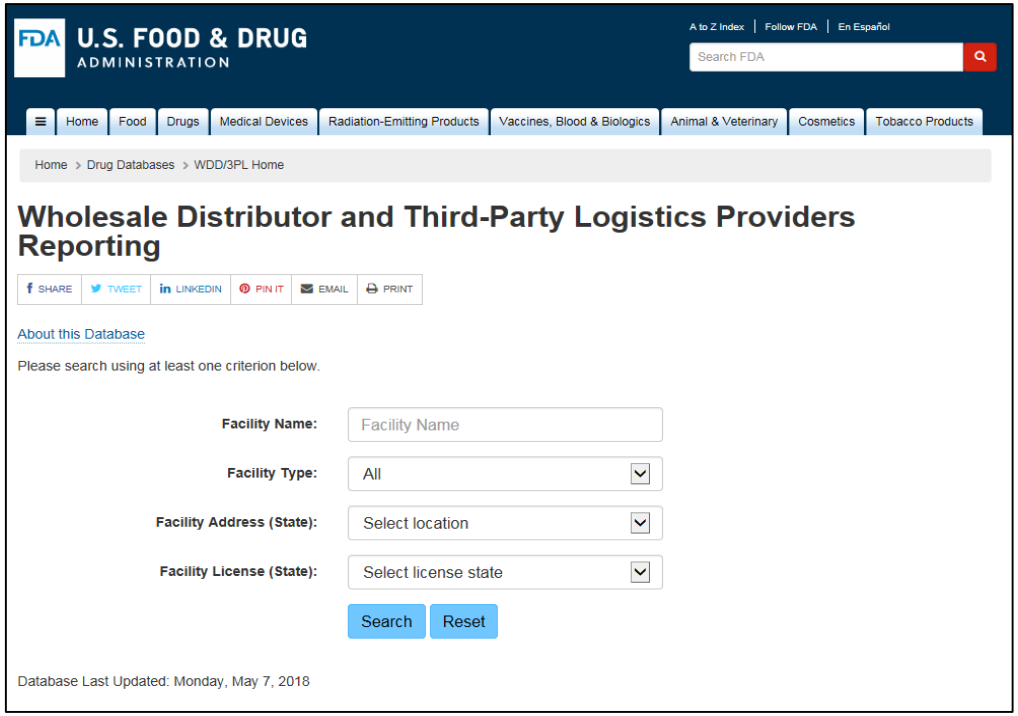
# FDA's Drug Establishment Current Registration Site (DECRS)




- DECRS publishes currently registered establishments (facilities) which manufacture, prepare, propagate, compound or process drugs that are commercially distributed in the U.S. or offered for import to the U.S.
- For DSCSA purposes, check DECRS for valid registration by manufacturers and repackagers

# Wholesale Distributor and 3PL Reporting Database

- Reporting licensure to FDA started in 2014 for 3PLs and in 2015 for wholesale distributors
- Single national database
- Self reported information by Wholesale Distributors and 3PLs
- Search capability (by facility name, type, State, or license)
- File download capability



# Product Tracing Requirement

| | |
|---|---|
| Receive | • When buying, only accept prescription drugs with product tracing information:<br>  • Transaction Information (TI)<br>  • Transaction History (TH)<br>  • Transaction Statement (TS)<br>CURRENTLY LOT-LEVEL |
| 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 for at le<br>CURRENTLY PAPER or ELECTRONIC |
| Return | •Return product to the trading partner that you bought the drug from |

# 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.

# 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

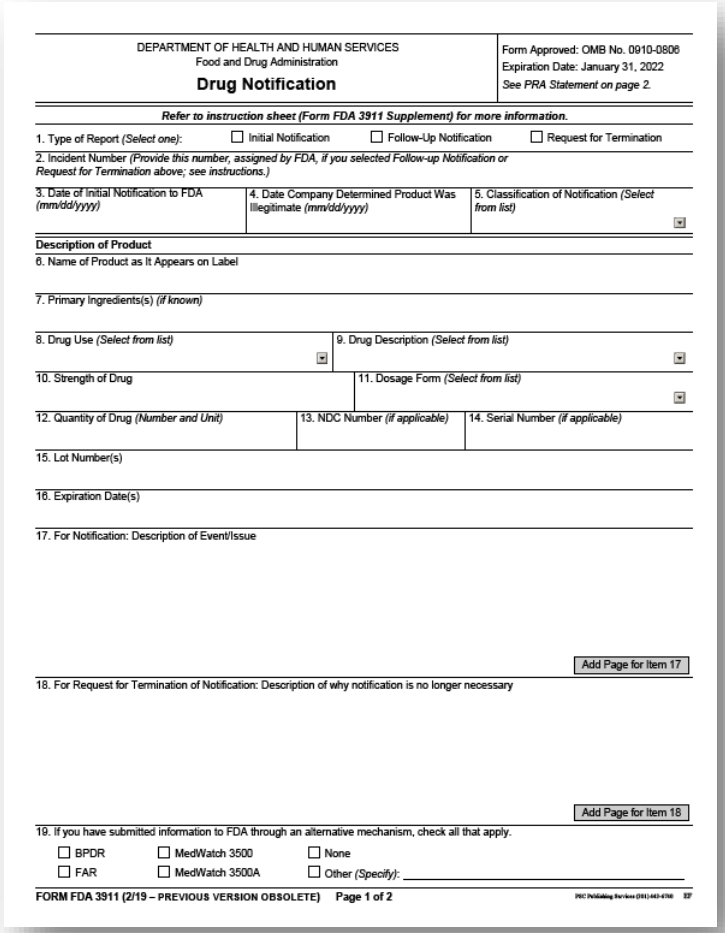
**Illegitimate Product:** ***credible evidence*** shows that the product is:

- 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

# Verification Requirements

| | |
|---|---|
| Quarantine and Investigate | • Suspect prescription drugs to determine if illegitimate |
| Investigation | • -- Must include validating applicable TI and TH<br>• -- 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 |

# Drug Notifications to FDA – Illegitimate Product



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

**Drug Notification**

Form Approved: OMB No. 0910-0806
Expiration Date: January 31, 2022
*See PRA Statement on page 2.*

***Refer to instruction sheet (Form FDA 3911 Supplement) for more information.***

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

2. Incident Number *(Provide this number, assigned by FDA, if you selected Follow-up Notification or Request for Termination above; see instructions.)*

3. Date of Initial Notification to FDA *(mm/dd/yyyy)*

4. Date Company Determined Product Was Illegitimate *(mm/dd/yyyy)*

5. Classification of Notification *(Select from list)*

**Description of Product**

6. Name of Product as It Appears on Label

7. Primary Ingredients(s) *(if known)*

8. Drug Use *(Select from list)*

9. Drug Description *(Select from list)*

10. Strength of Drug

11. Dosage Form *(Select from list)*

12. Quantity of Drug *(Number and Unit)*

13. NDC Number *(if applicable)*

14. Serial Number *(if applicable)*

15. Lot Number(s)

16. Expiration Date(s)

17. For Notification: Description of Event/Issue

Add Page for Item 17

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

Add Page for Item 18

19. If you have submitted information to FDA through an alternative mechanism, check all that apply.

☐ BPDR ☐ MedWatch 3500 ☐ None
☐ FAR ☐ MedWatch 3500A ☐ Other *(Specify)*: _____

**FORM FDA 3911 (2/19 – PREVIOUS VERSION OBSOLETE) Page 1 of 2**

Notify FDA within 24 hours using Form FDA 3911

Notify other trading partners within 24 hours

Request notification termination using Form FDA 3911

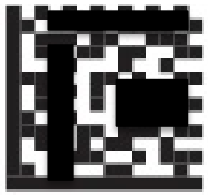
# Product Identifier Requirement (Serialization)

**Product Identifier**

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

- **Human and machine readable formats**
- **2D data matrix barcode for packages**
- **Linear or 2D data matrix barcode for homogenous cases**

**NDC: XXXX-XXXX-XX**
**SERIAL: XXXXXXXX**
**LOT: XXXXXXX**
**EXP: YYYY-MM-DD**



**Manufacturers/Repackagers**

- **Encode product identifiers on prescription drug packages (November 2018)**
- **Determine smallest individual saleable unit**

**Verification requirements change once products are serialized with product identifier**

# Regulations
# Wholesale Distributor/ Third-Party Logistics Provider Licensing and Standards

**Wholesale distributor (WDD)**

- WDD standards for licensure go into effect 2 years after the final regulation is published.
- The federal system for wholesale distributor licensing is used when the state from which the drug is distributed has not established a licensure requirement.

**Third-party logistics provider (3PL)**

- 3PL standards for licensure go into effect 1 year after the final regulation is published.
- No state shall regulate 3PLs as wholesale distributors.
- The federal system for 3PL licensing is used when the state from which the drug is distributed has not established a licensure requirement.

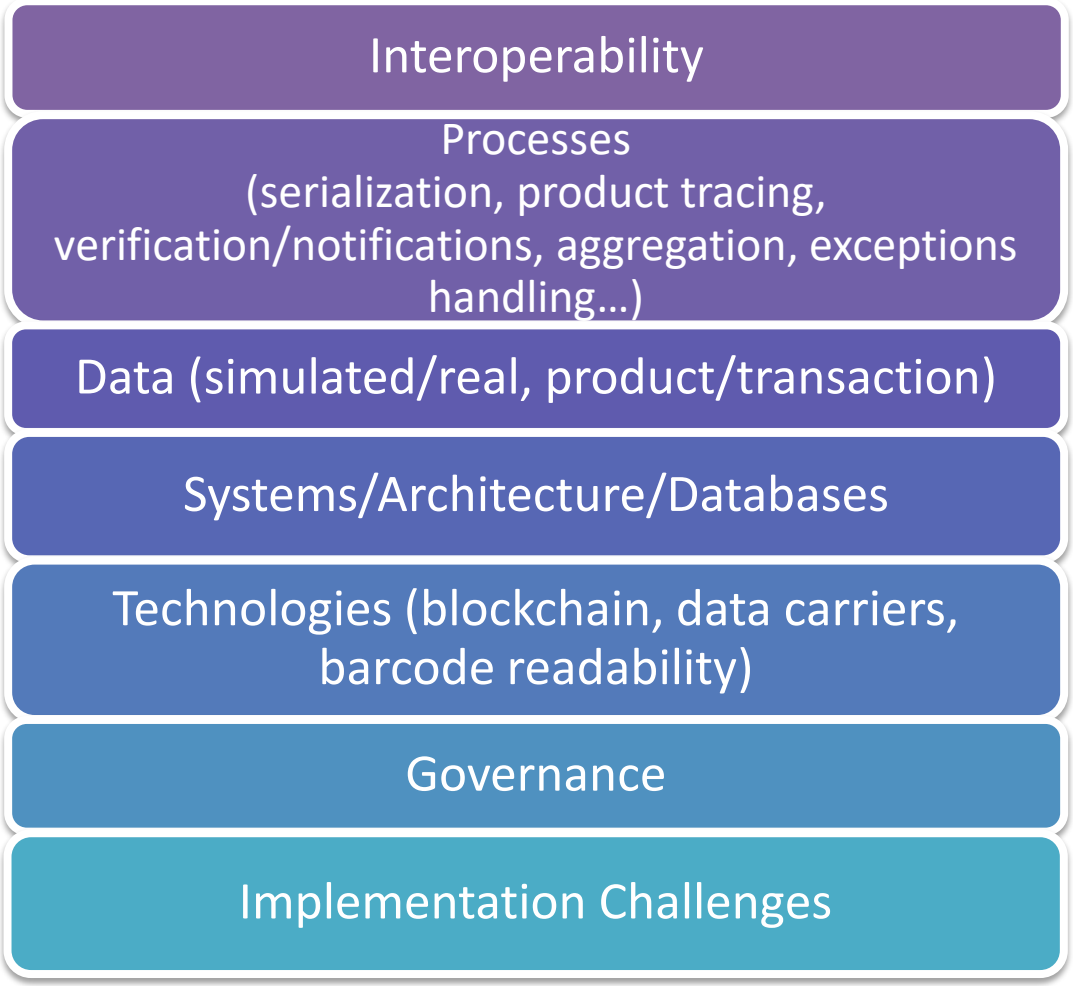
# DSCSA Pilot Project Program Goals

- Identify the system attributes needed to implement the requirements of section 582, particularly the requirement to utilize a product identifier for product tracing and verification purposes; and
- Assess the ability of supply chain members to:
  - satisfy the requirements of section 582 of the FD&C Act;
  - identify, manage, and prevent the distribution of suspect and illegitimate products as defined in section 581(21) and 581(8) of the FD&C Act, respectively, and
  - exchange product tracing information across the pharmaceutical distribution supply chain in an electronic and interoperable manner

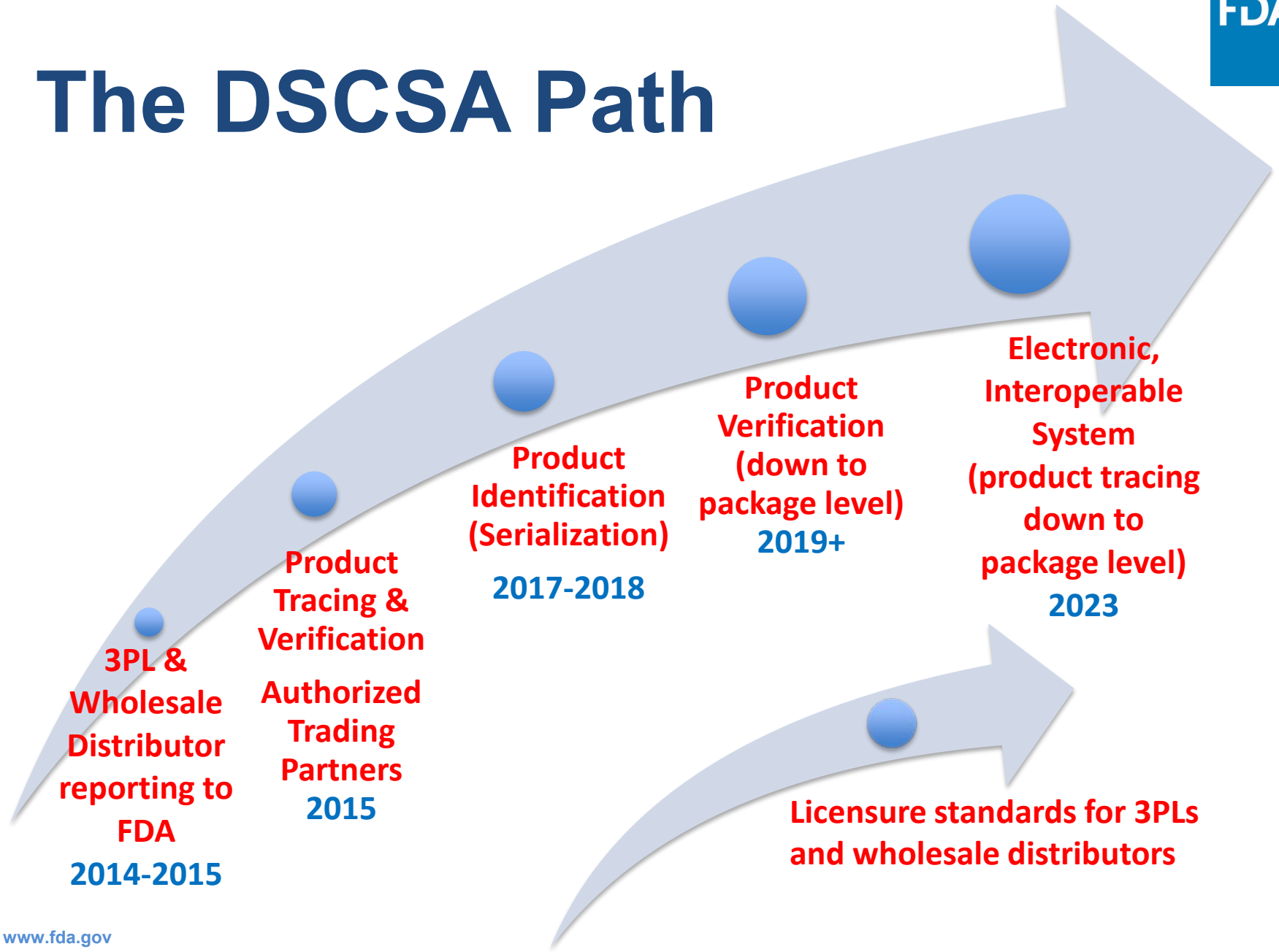
# DSCSA Pilot Project Program


Estimated Timeline for Pilot Projects and Progress Reports

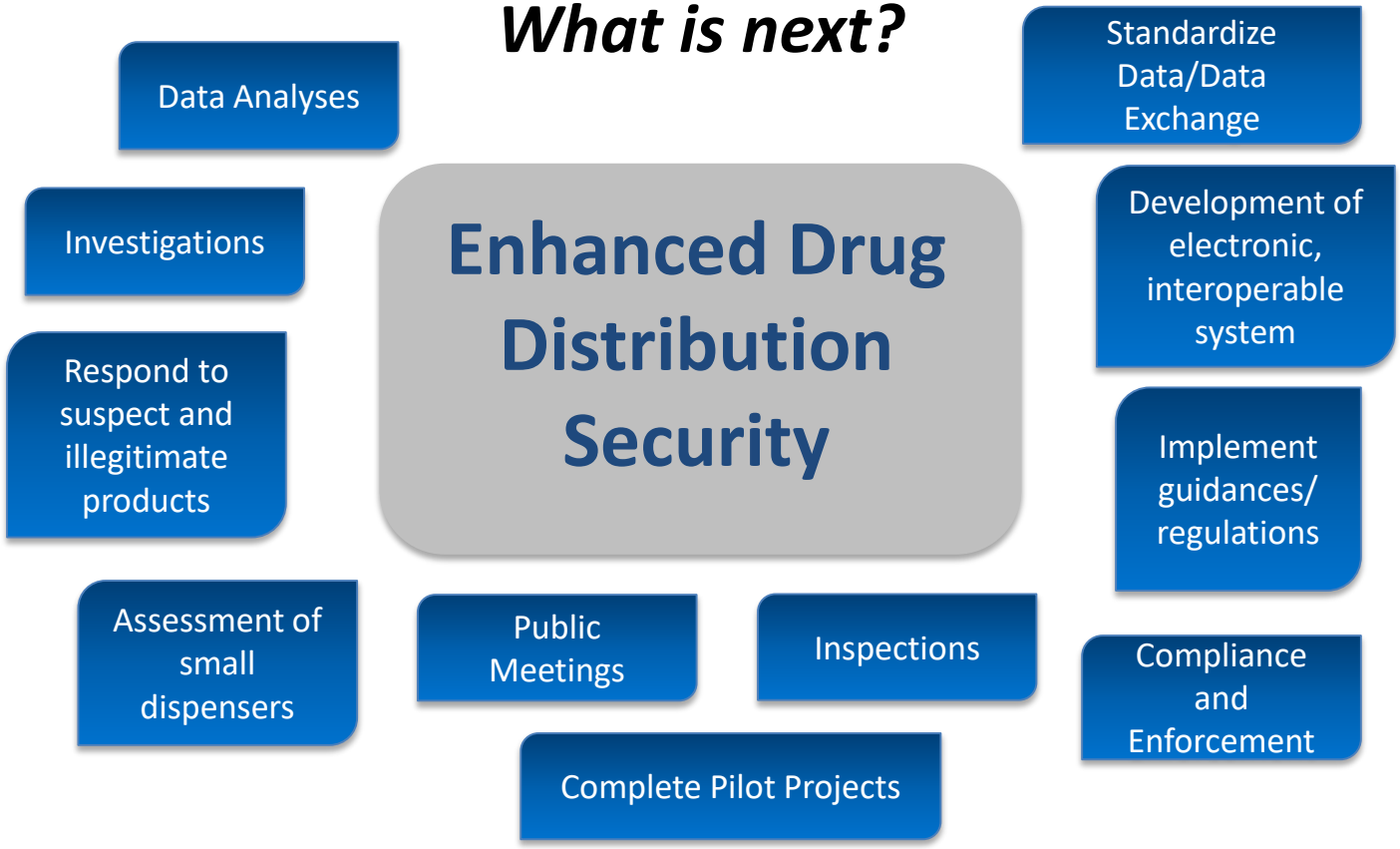
# DSCSA Pilot Projects



# The DSCSA Path



# *What is next?*


Enhanced Drug Distribution Security
Data Analyses
Standardize Data/Data Exchange
Investigations
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

# Resources

- DSCSA 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