

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



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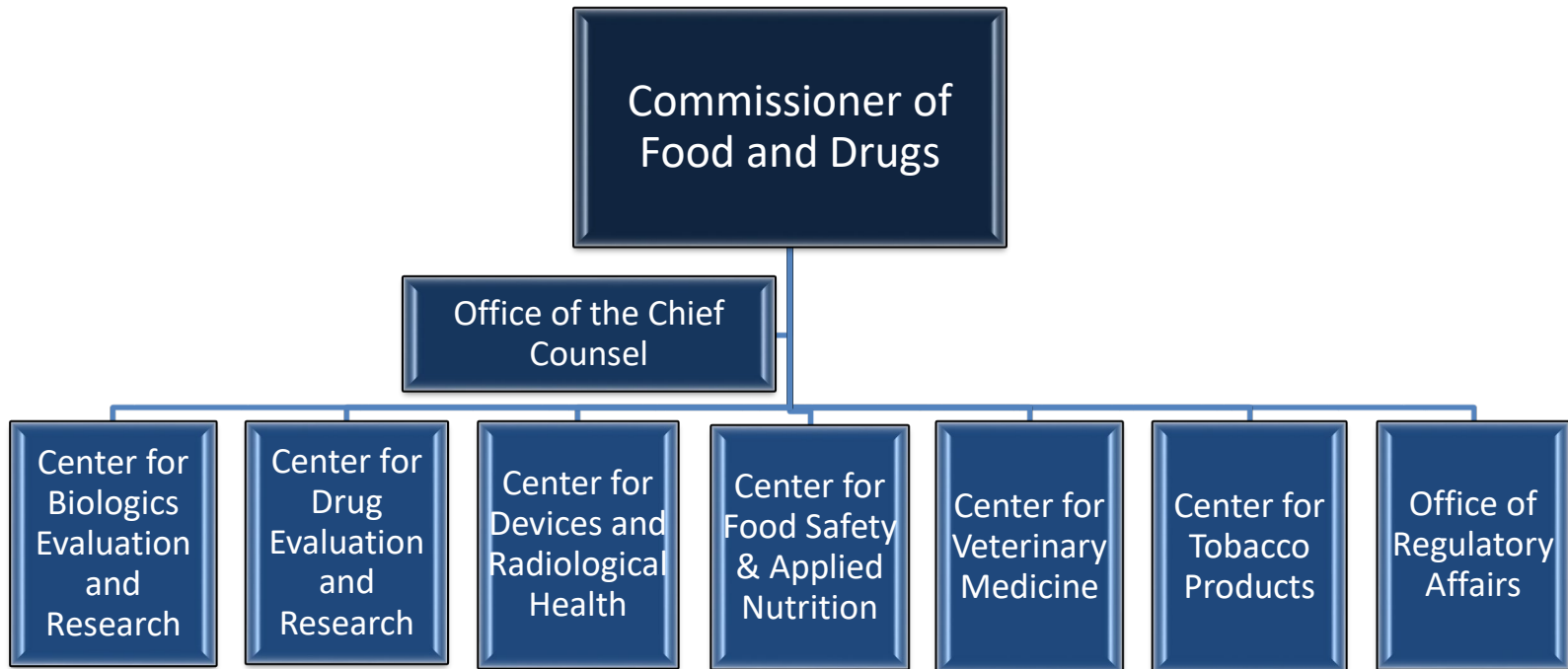
*Global GS1 Healthcare Conference  
November 5, 2019  
New Delhi, India*

# 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.**

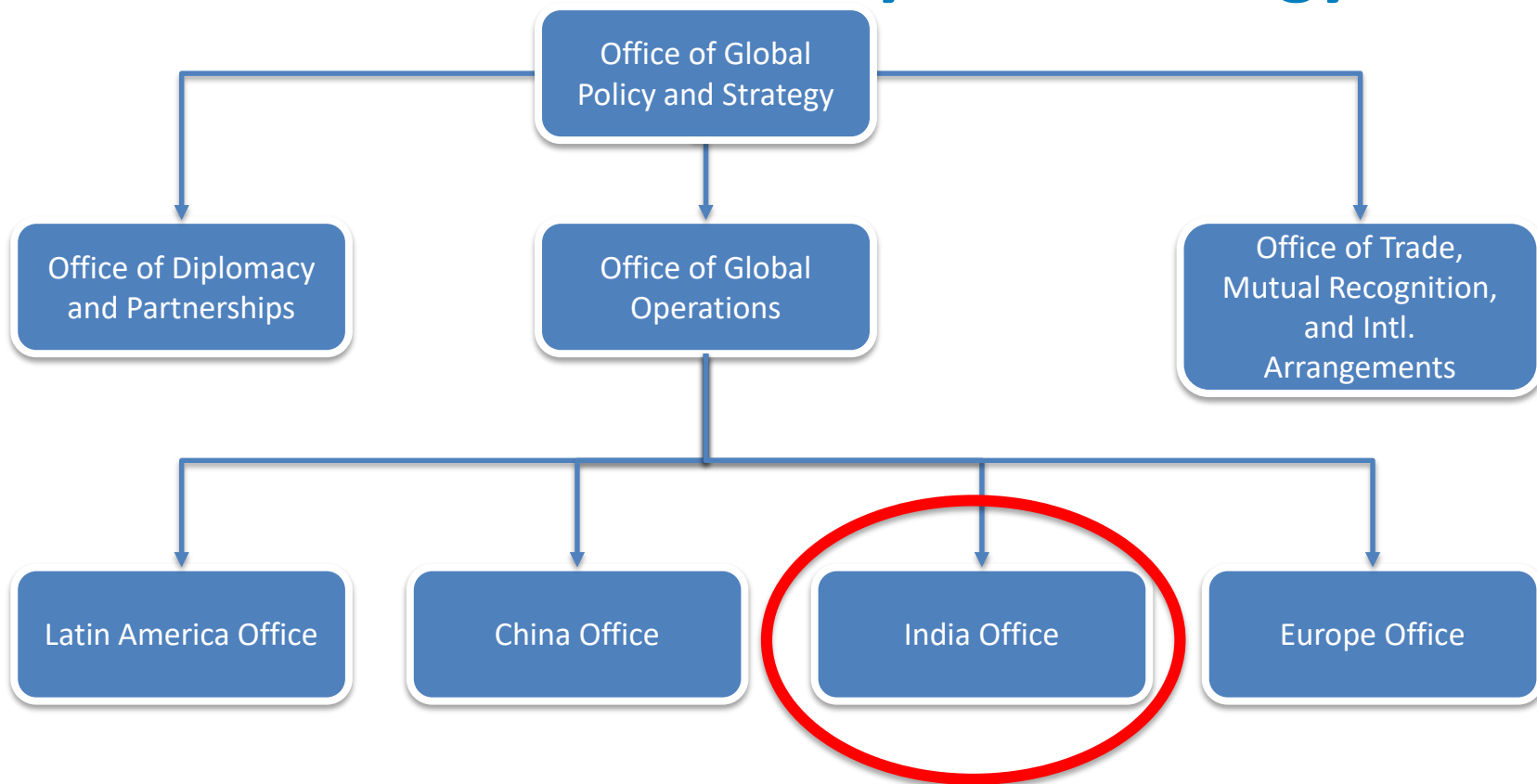
## Additional Resources

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



(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.

STRATEGIC PRIORITY 1:  
**POLICY  
COHERENCE**



Promote mutually reinforcing policy actions to advance FDA's public health and regulatory interests globally.

STRATEGIC PRIORITY 2:  
**GLOBAL  
PARTNERSHIPS**



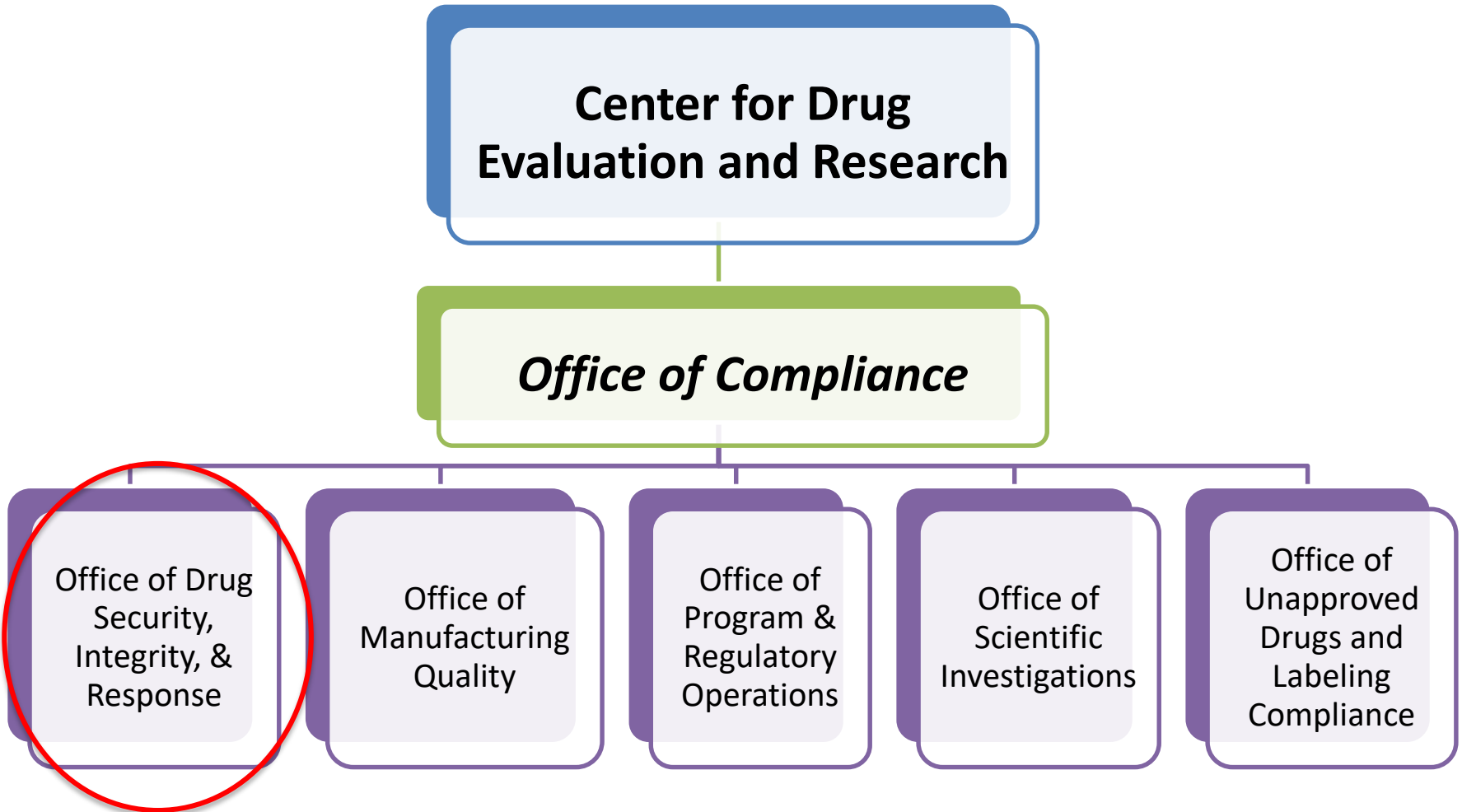
Build and leverage global partnerships to protect and promote public health.

STRATEGIC PRIORITY 3:  
**HIGH QUALITY  
INFORMATION**

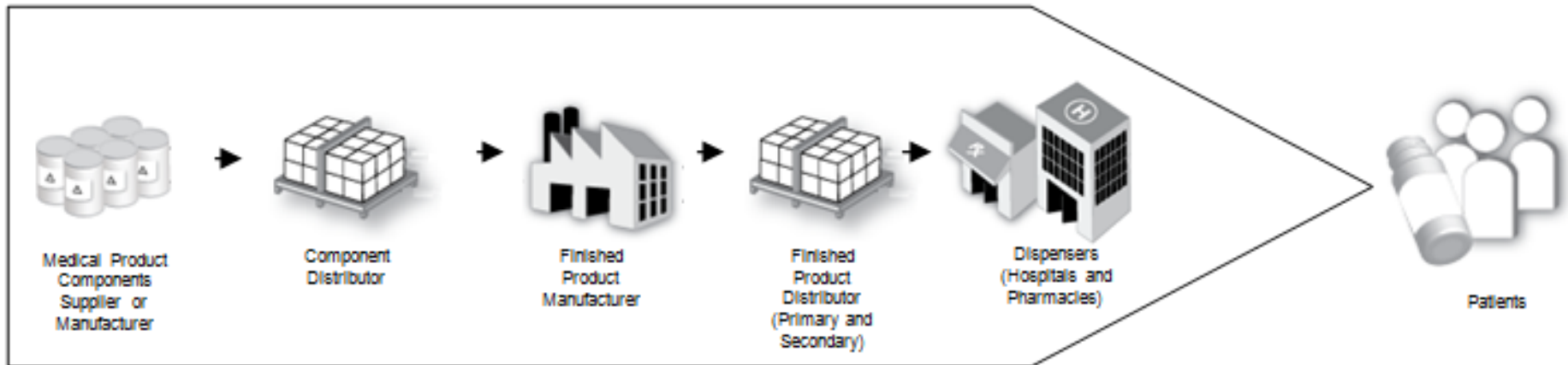


Collect, analyze, and share *high-quality* information, including inspections data, to advance FDA's public health mission.

# 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**

Offices of the United States Attorneys United States Department of Justice

THE UNITED STATES ATTORNEY'S OFFICE  
EASTERN DISTRICT of VIRGINIA

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FOR IMMEDIATE RELEASE Friday, January 18, 2019

**Medical Company Executive Sentenced for Smuggling \$18 Million in Misbranded Pharmaceuticals into United States**

Offices of the United States Attorneys United States Department of Justice

THE UNITED STATES ATTORNEY'S OFFICE  
DISTRICT of MONTANA

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FOR IMMEDIATE RELEASE Friday, April 13, 2018

**Canadian Drug Wholesaler Sentenced for Selling Counterfeit and Misbranded Drugs Throughout the 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](#)

FOR IMMEDIATE RELEASE

**Second Turkish man sentenced for smuggling counterfeit cancer drugs**

*Other business partner in drug wholesaling scheme was sentenced in October 2014*

Department of Justice  
U.S. Attorney

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FOR IMMEDIATE RELEASE Friday, May 9, 2014

**Illegal Distribution of Counterfeit Avastin by Gallant Pharma And Co-Founder Sentenced**

**Counterfeit Version of Avastin in U.S. Distribution**

[f SHARE](#) [TWEET](#) [LINKEDIN](#) [PIN IT](#) [EMAIL](#) [PRINT](#)

Statement Update Issued: July 10, 2012

**Protecting the supply chain ultimately protects patients!**



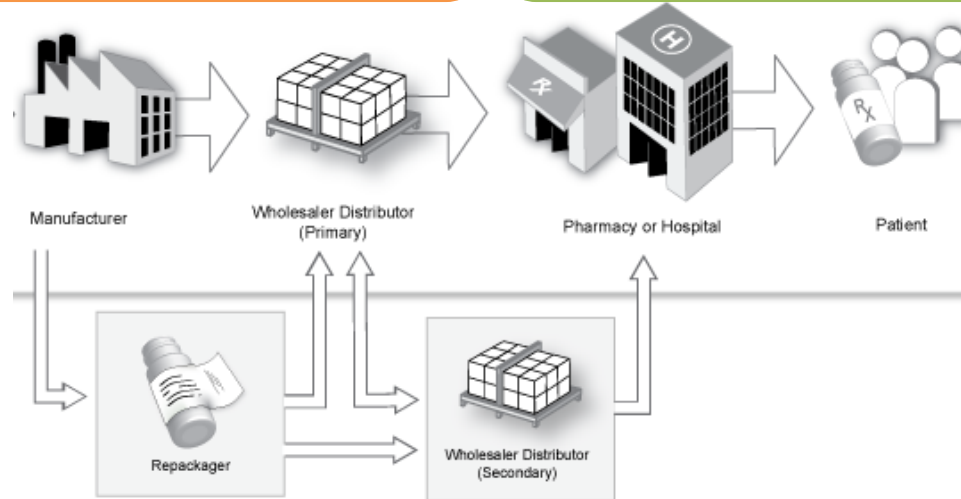
# Threats to the Pharmaceutical Supply Chain

## 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

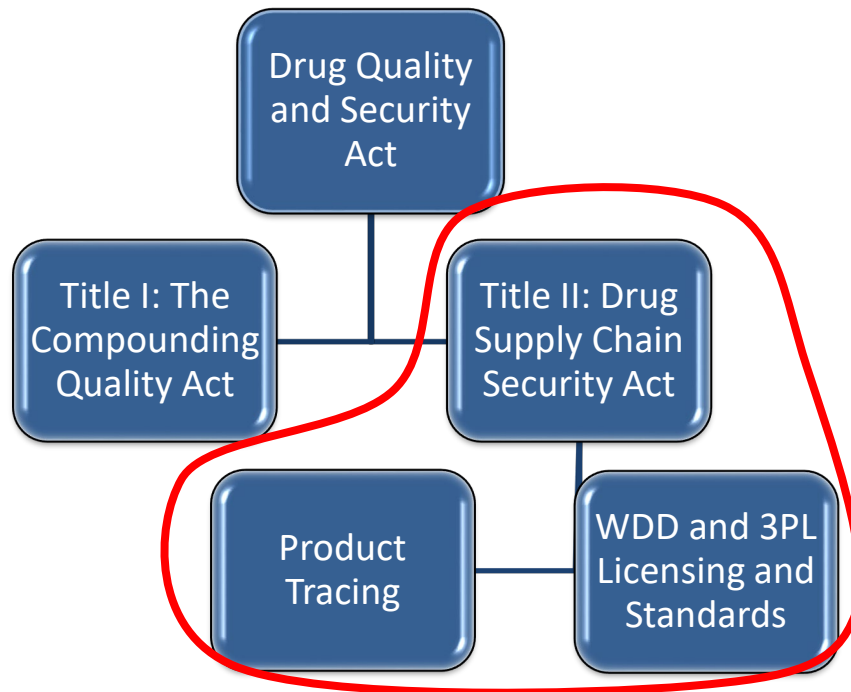
- Distribute illegitimate product
- Don't maintain quality of the product
- Don't maintain security or integrity of the supply chain (examples: are not authorized or do business with entities that are not authorized)



***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



**Prevent** harmful drugs from entering the supply chain.

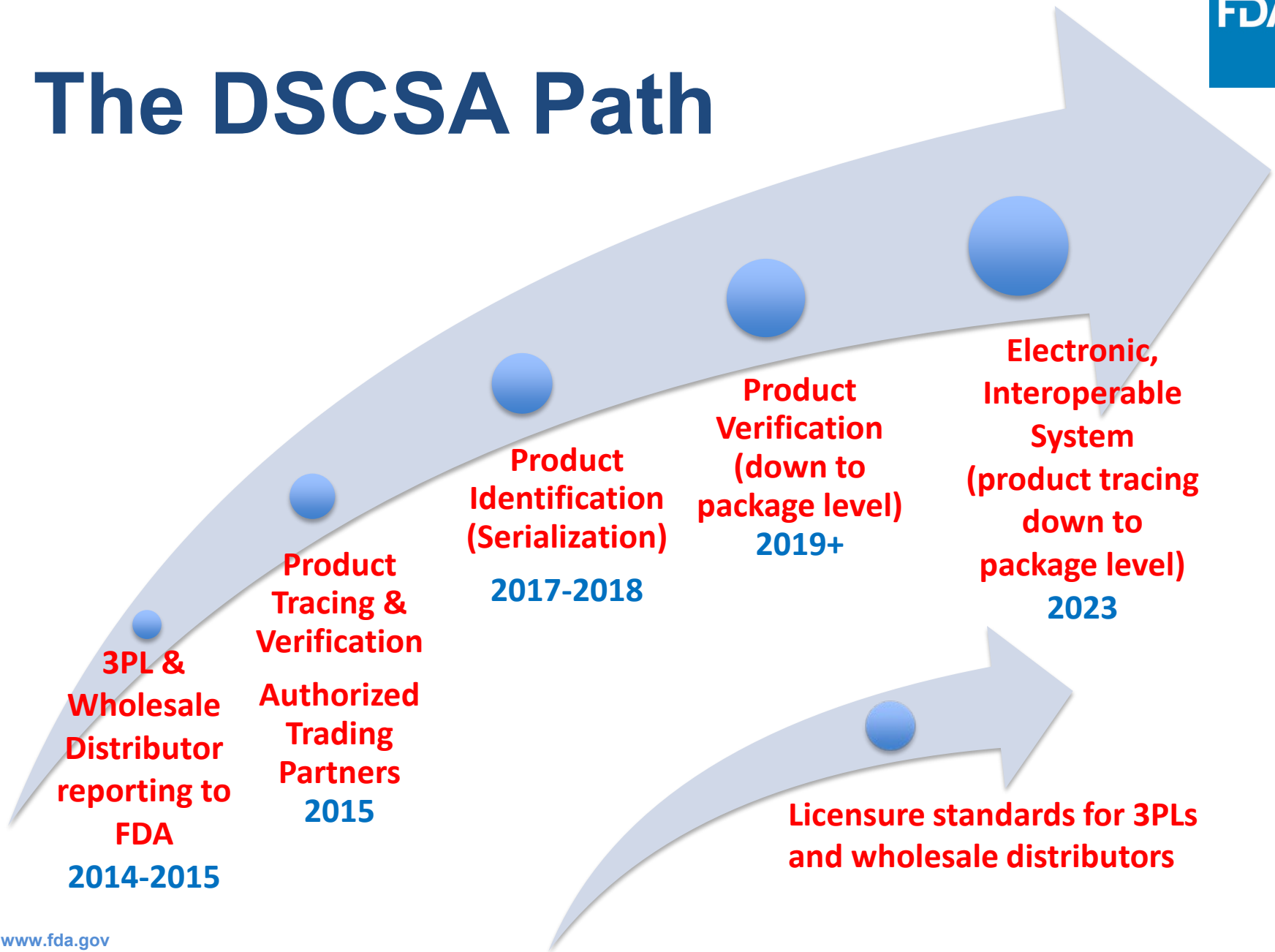


**Detect** harmful drugs if they enter the supply chain.



**Respond** rapidly when harmful drugs are found.

# 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

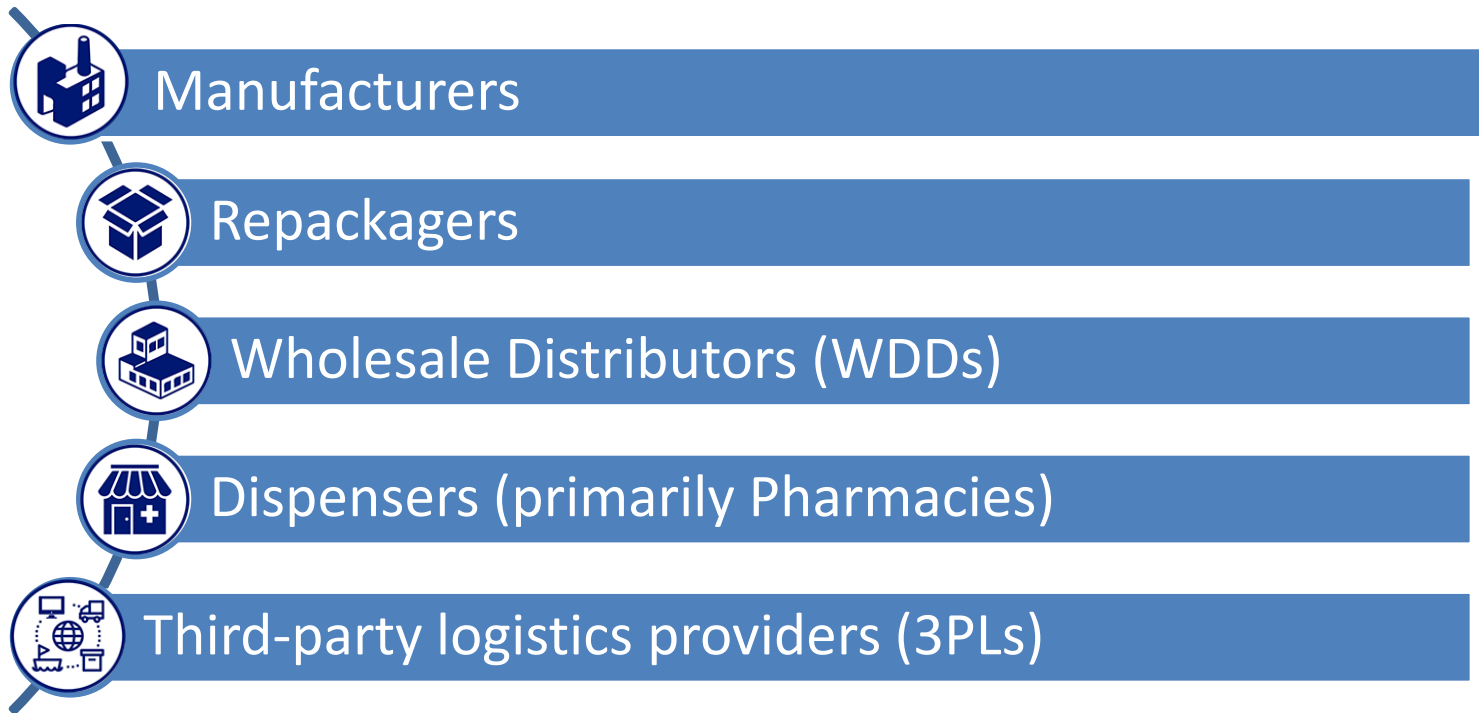
*Refer to the definition for “product” in section 581(13) of the FD&C Act for specific information regarding exceptions.*

# 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

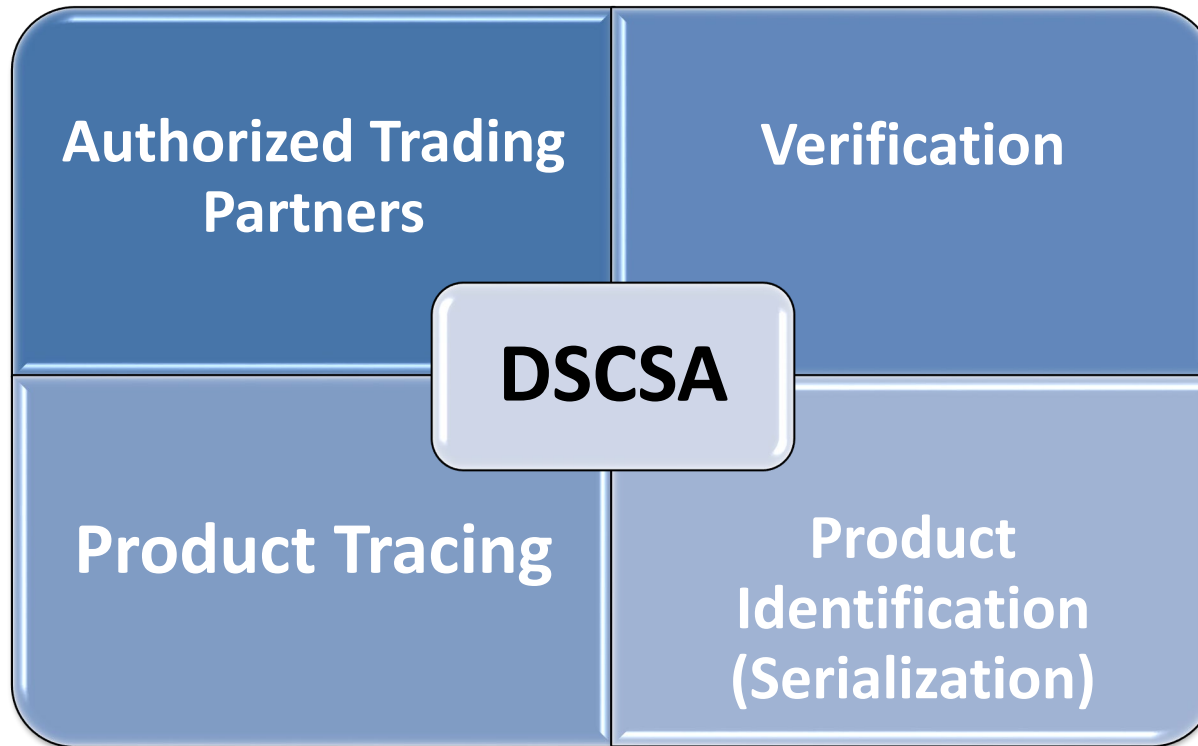
*Refer to the definition for “transaction” in section 581(24) of the FD&C Act for specific information regarding exclusions.*

# 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

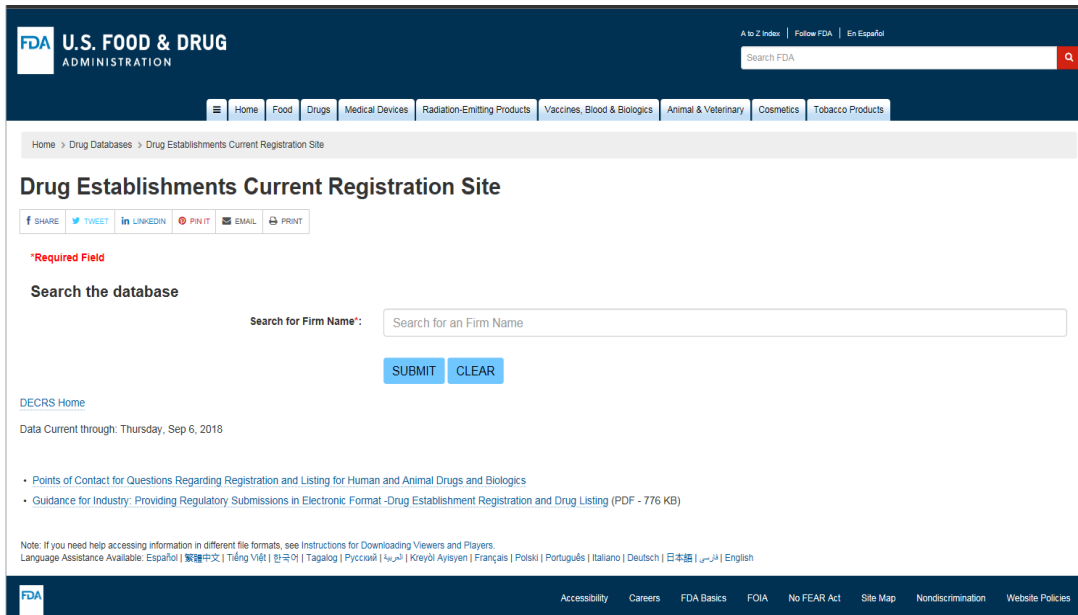
- Have valid State or Federal license and compliance with reporting requirements
- Check FDA's WDD/3PL database

## Dispensers

- Have valid State license
- Check respective state authorities

Trading partners must be authorized!

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

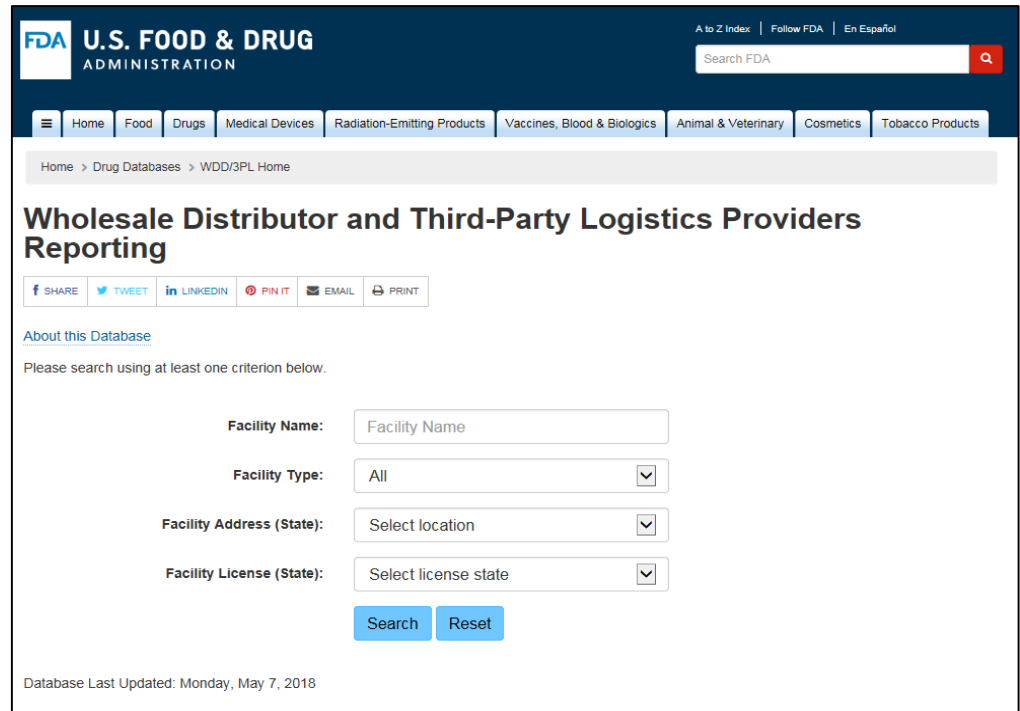


The screenshot shows the FDA's Drug Establishment Current Registration Site (DECRS) search interface. At the top, there is the FDA logo and the text "U.S. FOOD & DRUG ADMINISTRATION". Below this is a navigation menu with links for Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products. A search bar is located in the top right corner. The main content area features the title "Drug Establishments Current Registration Site" and a search form. The search form includes a "Search for Firm Name\*" label and a text input field with the placeholder "Search for an Firm Name". Below the input field are "SUBMIT" and "CLEAR" buttons. There are also social media sharing options (SHARE, TWEET, LINKEDIN, PINTEREST, EMAIL, PRINT) and a "Required Field" indicator. At the bottom of the page, there is a footer with the FDA logo and links for Accessibility, Careers, FDA Basics, FOIA, No FEAR Act, Site Map, Nondiscrimination, and Website Policies.

- 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



The screenshot shows the FDA's reporting database search page. At the top, there is the FDA logo and navigation links for 'Home', 'Food', 'Drugs', 'Medical Devices', 'Radiation-Emitting Products', 'Vaccines, Blood & Biologics', 'Animal & Veterinary', 'Cosmetics', and 'Tobacco Products'. A search bar is located in the top right corner. Below the navigation, the page title is 'Wholesale Distributor and Third-Party Logistics Providers Reporting'. There are social media sharing options for Facebook, Twitter, LinkedIn, Pinterest, Email, and Print. A link for 'About this Database' is also present. The main search area prompts the user to 'Please search using at least one criterion below.' and includes four search criteria: 'Facility Name' (text input), 'Facility Type' (dropdown menu), 'Facility Address (State)' (dropdown menu), and 'Facility License (State)' (dropdown menu). 'Search' and 'Reset' buttons are located at the bottom of the search area. At the very bottom, it states 'Database Last Updated: Monday, May 7, 2018'.

# Product Tracing Requirement

## Receive

- When buying, only accept prescription drugs with product tracing information:
  - Transaction Information (TI)
  - Transaction History (TH)
  - Transaction Statement (TS)

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 least

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	<ul style="list-style-type: none"><li>• Suspect prescription drugs to determine if illegitimate</li></ul>
Investigation	<ul style="list-style-type: none"><li>• -- Must include validating applicable TI and TH</li><li>• -- Once product is serialized, trading partners will need to verify lot number and product identifier</li></ul>
Notify	<ul style="list-style-type: none"><li>• If the product is illegitimate, notify FDA and certain immediate trading partners within 24 hours</li></ul>
Respond	<ul style="list-style-type: none"><li>• If the product is illegitimate, work with manufacturer to take steps to prevent it from reaching patients</li></ul>
Store	<ul style="list-style-type: none"><li>• Store records of investigation of suspect product and the disposition of illegitimate product for at least 6 years</li></ul>



# Drug Notifications to FDA – Illegitimate Product

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration <b>Drug Notification</b>		Form Approved: OMB No. 0910-0806 Expiration Date: January 31, 2022 See PRA Statement on page 2.
<b>Refer to instruction sheet (Form FDA 3911 Supplement) for more information.</b>		
1. Type of Report (Select one): <input type="checkbox"/> Initial Notification <input type="checkbox"/> Follow-Up Notification <input type="checkbox"/> 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) <input type="checkbox"/>
<b>Description of Product</b>		
6. Name of Product as It Appears on Label		
7. Primary Ingredients(s) (if known)		
8. Drug Use (Select from list) <input type="checkbox"/>	9. Drug Description (Select from list) <input type="checkbox"/>	
10. Strength of Drug	11. Dosage Form (Select from list) <input type="checkbox"/>	
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		
		<b>Add Page for Item 17</b>
18. For Request for Termination of Notification: Description of why notification is no longer necessary		
		<b>Add Page for Item 18</b>
19. If you have submitted information to FDA through an alternative mechanism, check all that apply.		
<input type="checkbox"/> BPDR	<input type="checkbox"/> MedWatch 3500	<input type="checkbox"/> None
<input type="checkbox"/> FAR	<input type="checkbox"/> MedWatch 3500A	<input type="checkbox"/> 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

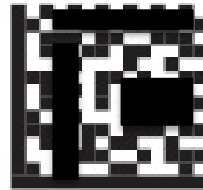
# Product Identifier Requirement (Serialization)

## 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: XXXXXXXX  
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

Interoperability

Processes  
(serialization, product tracing,  
verification/notifications, aggregation, exceptions  
handling...)

Data (simulated/real, product/transaction)

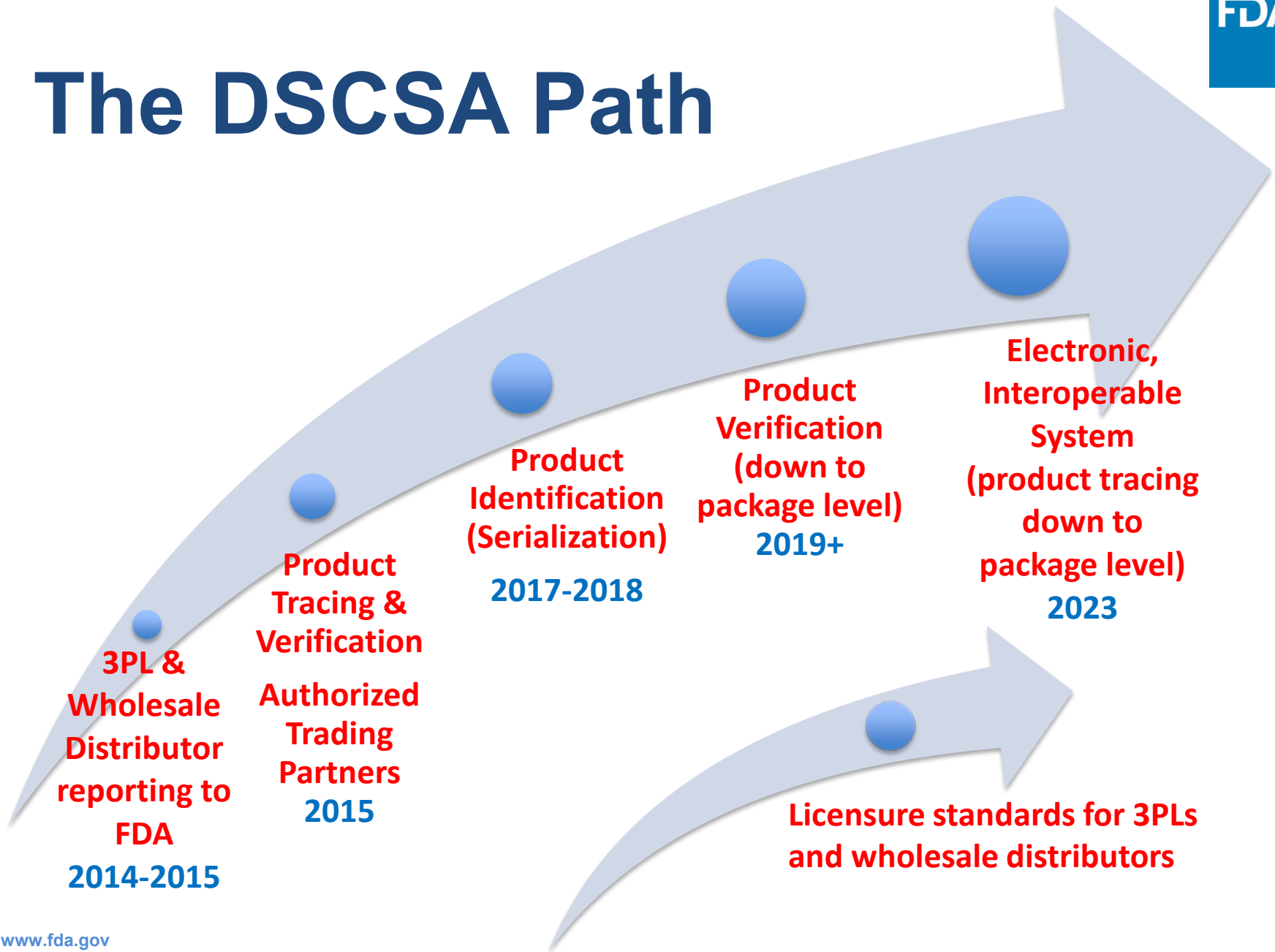
Systems/Architecture/Databases

Technologies (blockchain, data carriers,  
barcode readability)

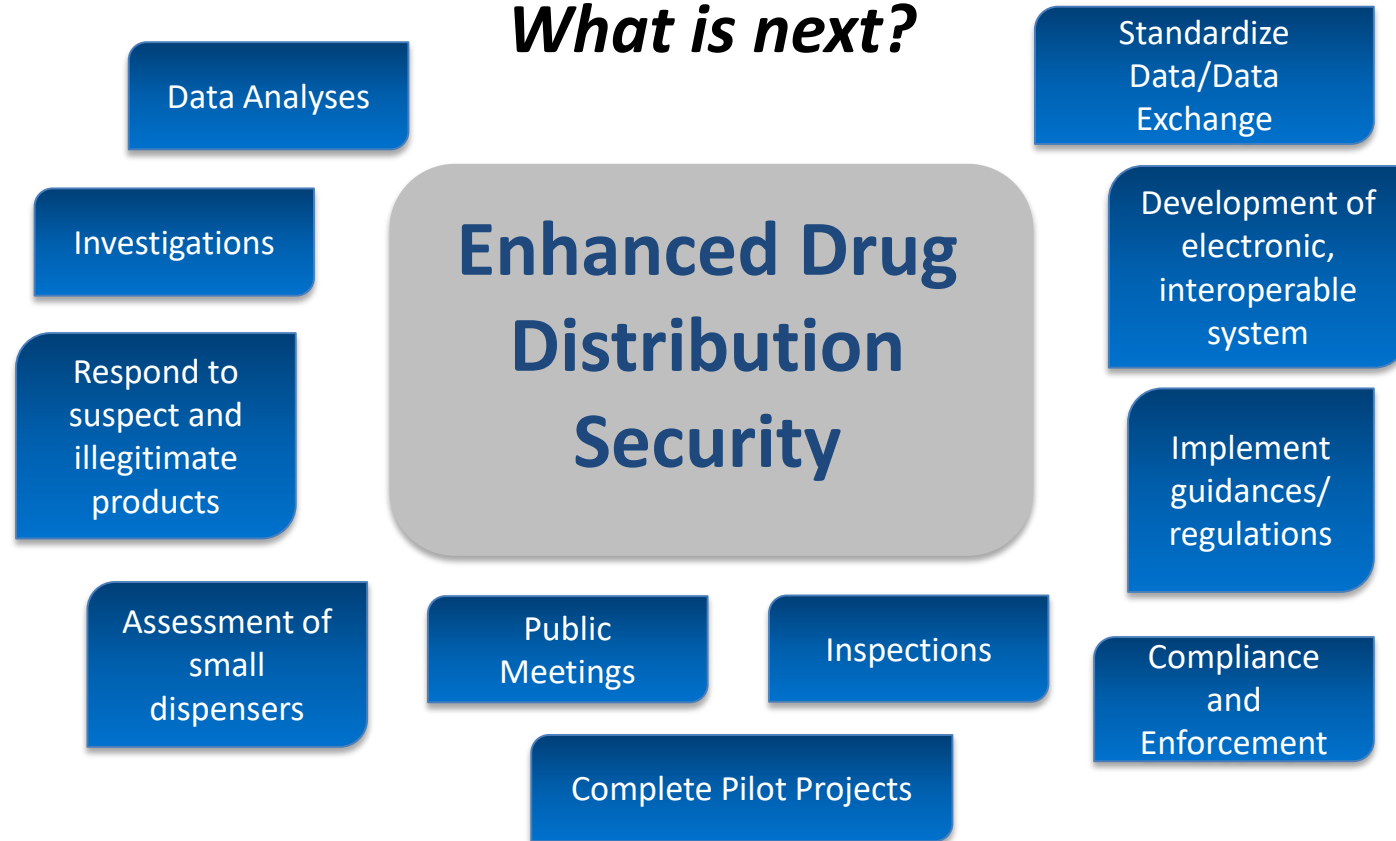
Governance

Implementation Challenges

# The DSCSA Path



## *What is next?*





# 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>