U.S. FDA
Medical Product Supply Chain Security and Traceability Efforts

FDA/CDER/Office of Compliance
Office of Drug Security, Integrity and Response

March 2021

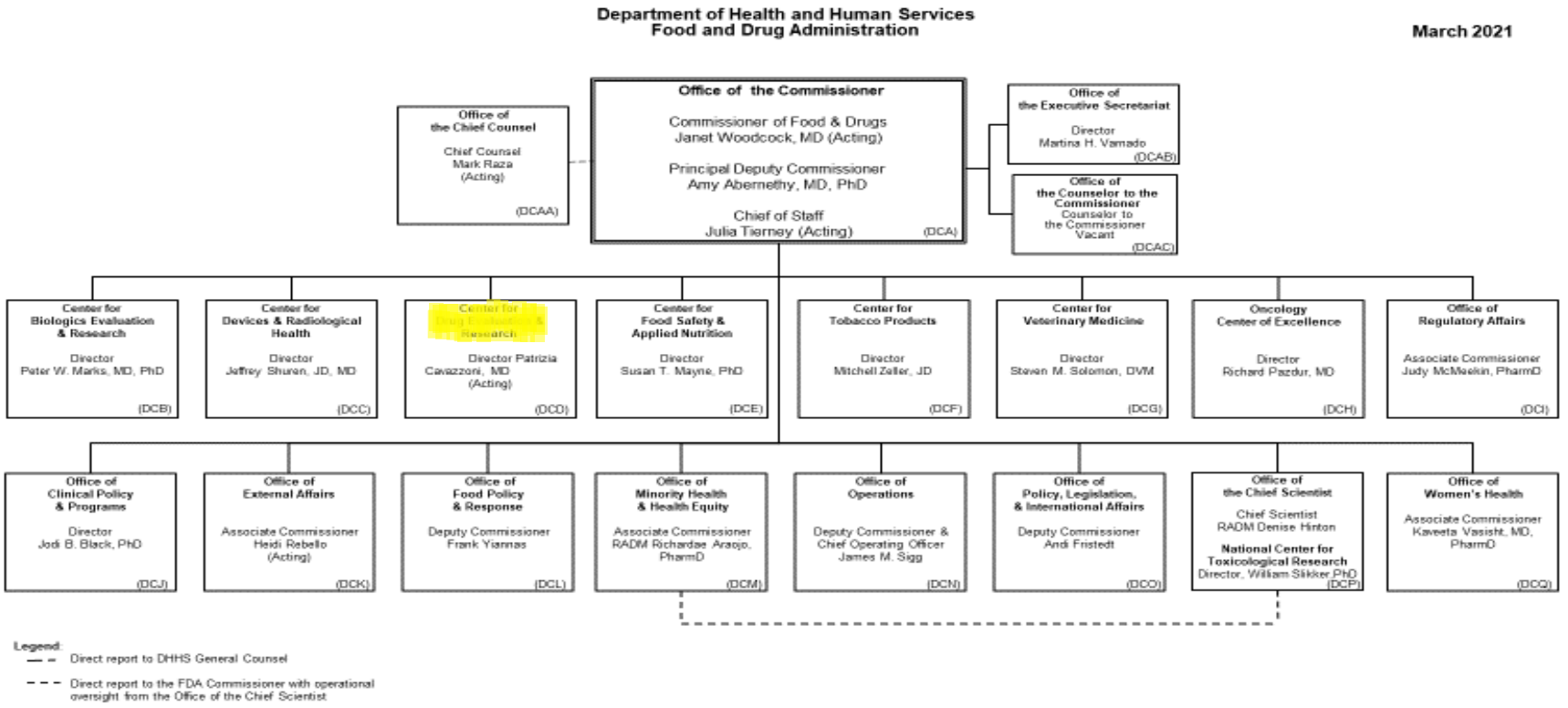
The U.S. Food and Drug Administration

- The Food and Drug Administration (FDA) is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation; FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

- FDA is responsible for advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health.

- FDA also plays a significant role in the U.S.'s counterterrorism capability. FDA fulfills this responsibility by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats.

The U.S. FDA Organization



FDA's Center for Drug Evaluation & Research

- The Center for Drug Evaluation and Research (CDER) performs an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States.

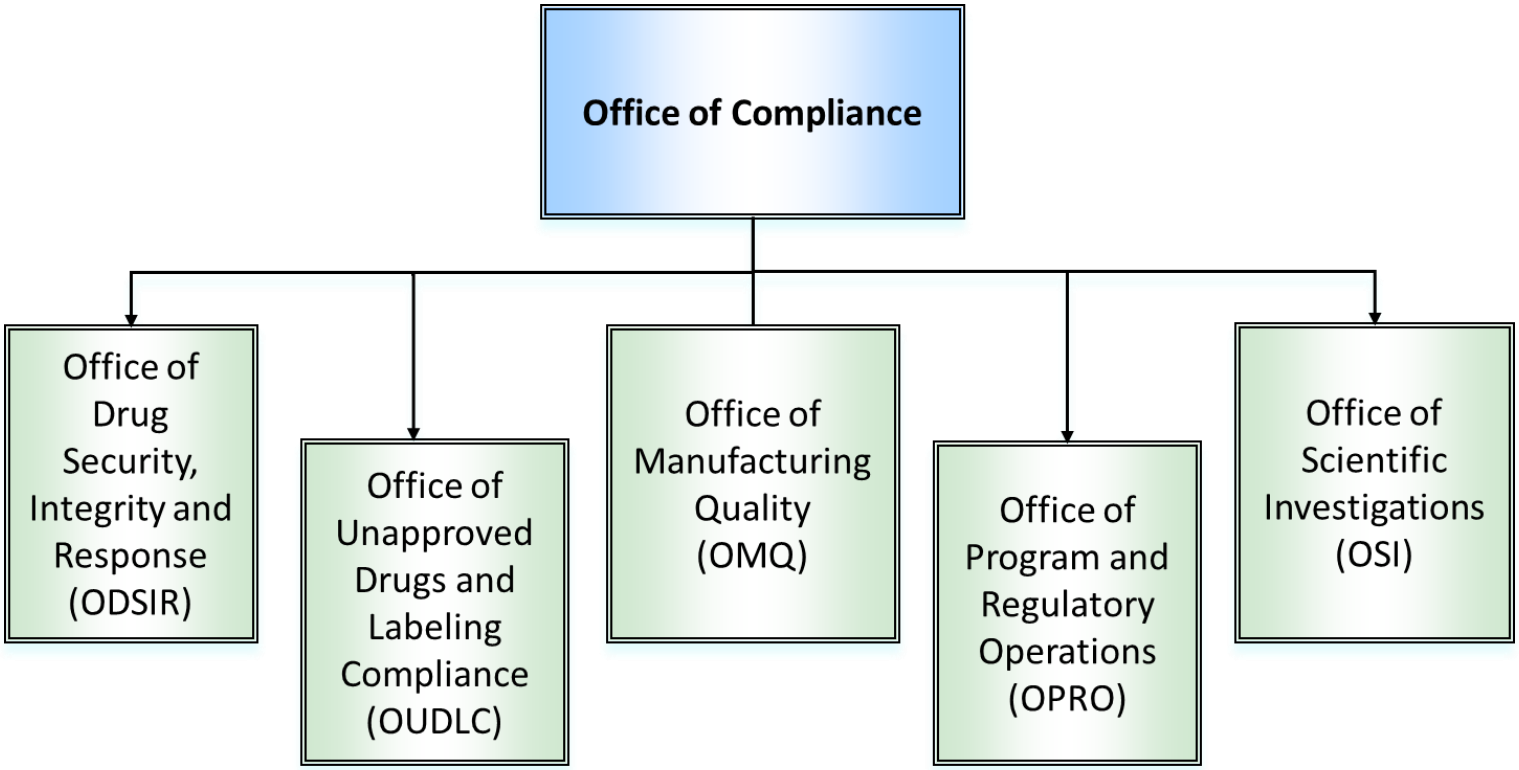
- As part of the U.S. Food and Drug Administration (FDA), CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This work covers more than just medicines. For example, fluoride toothpaste, antiperspirants, dandruff shampoos and sunscreens are all considered drugs.

CDER Office of Compliance

MISSION

To shield patients from poor quality, unsafe and ineffective drugs through proactive compliance strategies and risk-based enforcement action.

CDER Office of Compliance



Global Drug Manufacturing Supply Chain

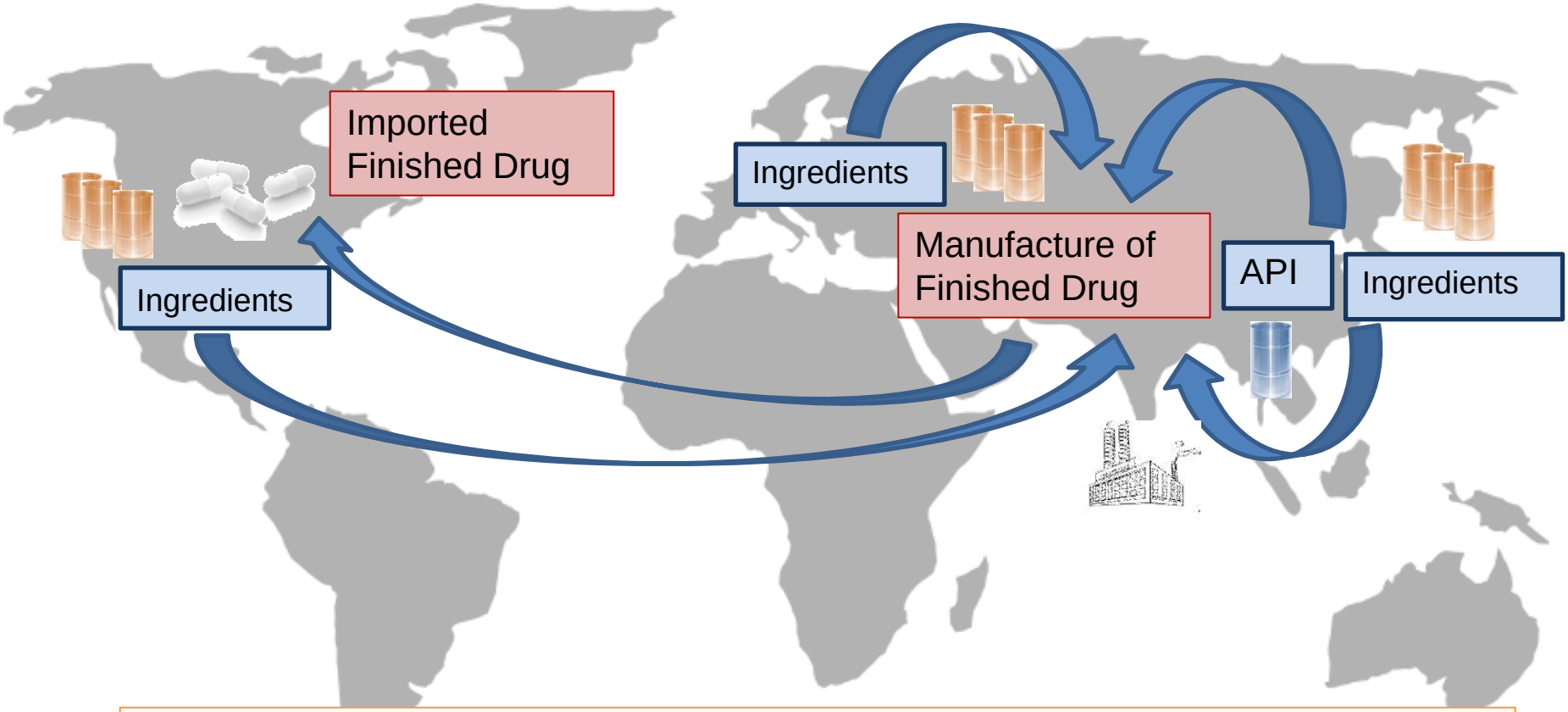
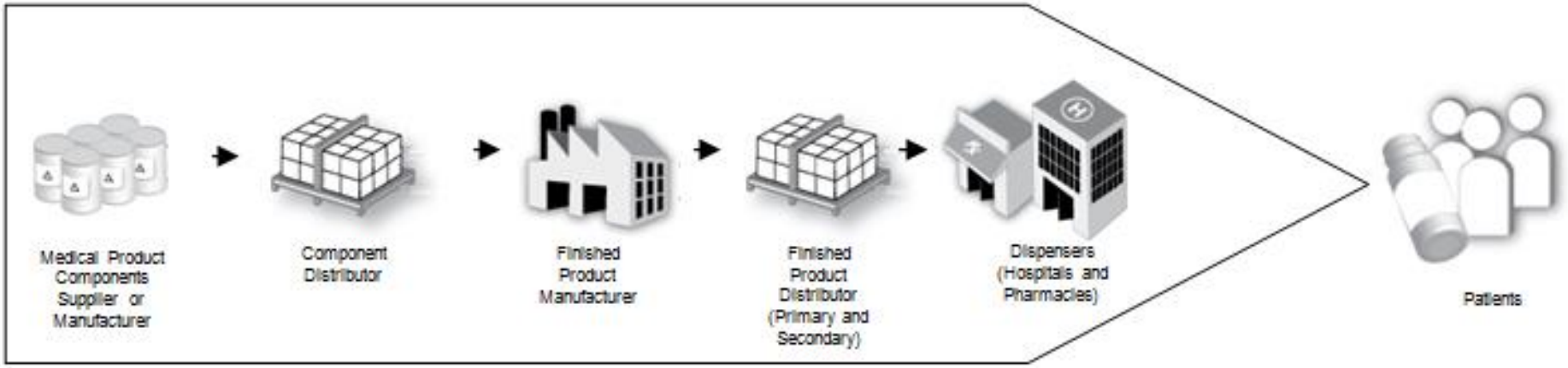


Illustration of drug manufacturing supply chain: A U.S. finished drug may be produced using an active pharmaceutical ingredient (API) made in China and ingredients made in Europe, Japan, or the U.S. These components may be shipped to India where the finished drug is manufactured and then imported into the U.S. for distribution.

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**

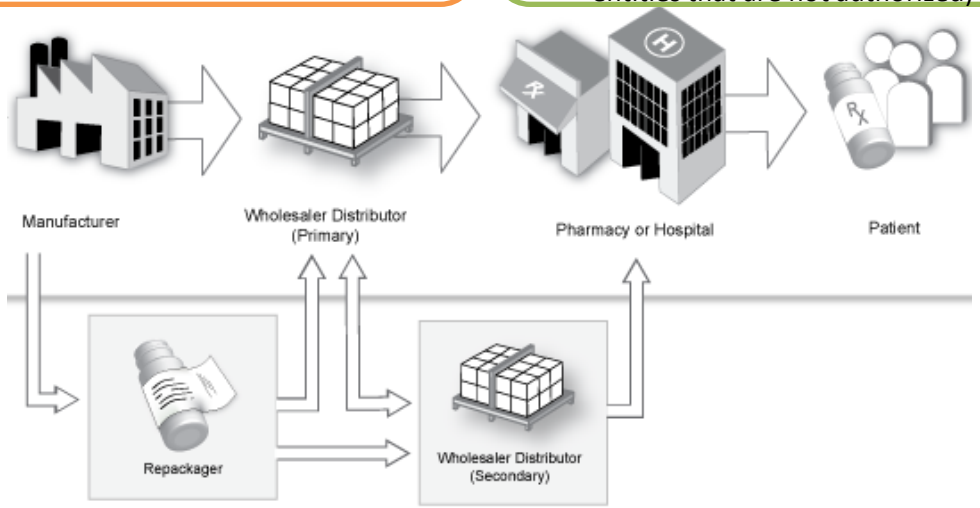
Threats to the Pharmaceutical Supply Chain

Illegitimate product

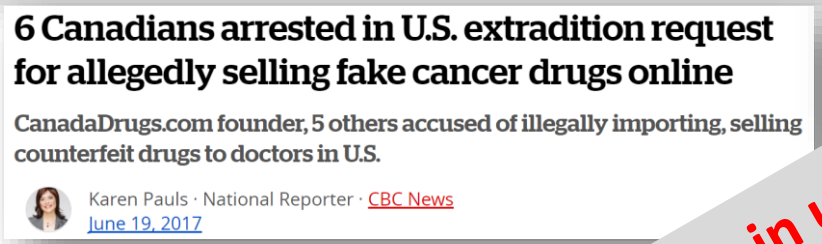
Counterfeit, diverted, stolen, intentionally adulterated, subject to a fraudulent transaction, or otherwise unfit for distribution that would result in serious adverse health consequences or death to humans

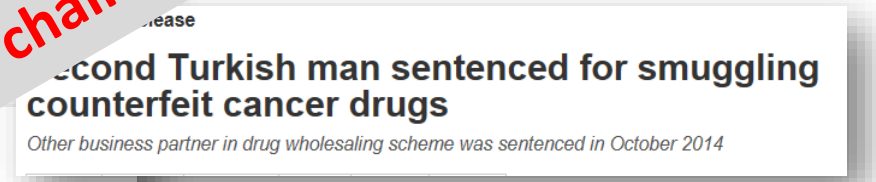
Unscrupulous players

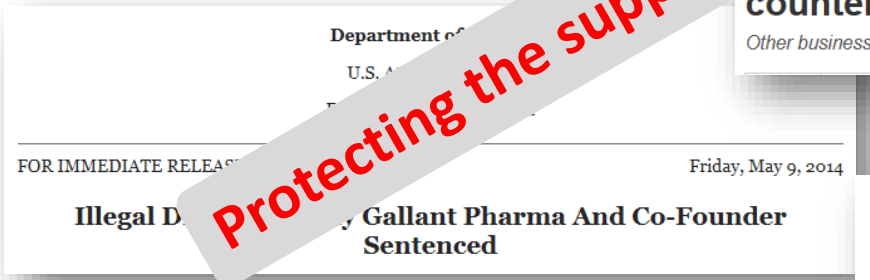
- Distribute illegitimate product
- Don't maintain quality of the product
- Don't maintain security or integrity of the supply chain (examples: are not authorized or do business with entities that are not authorized)

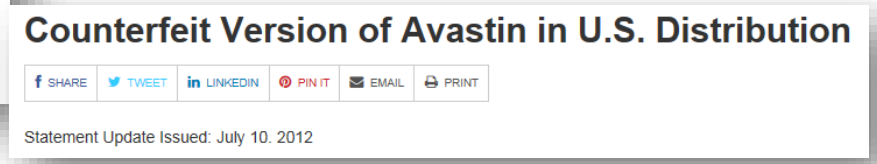


Weakness in the drug supply chain can be anywhere









Protecting the supply chain ultimately protects patients!

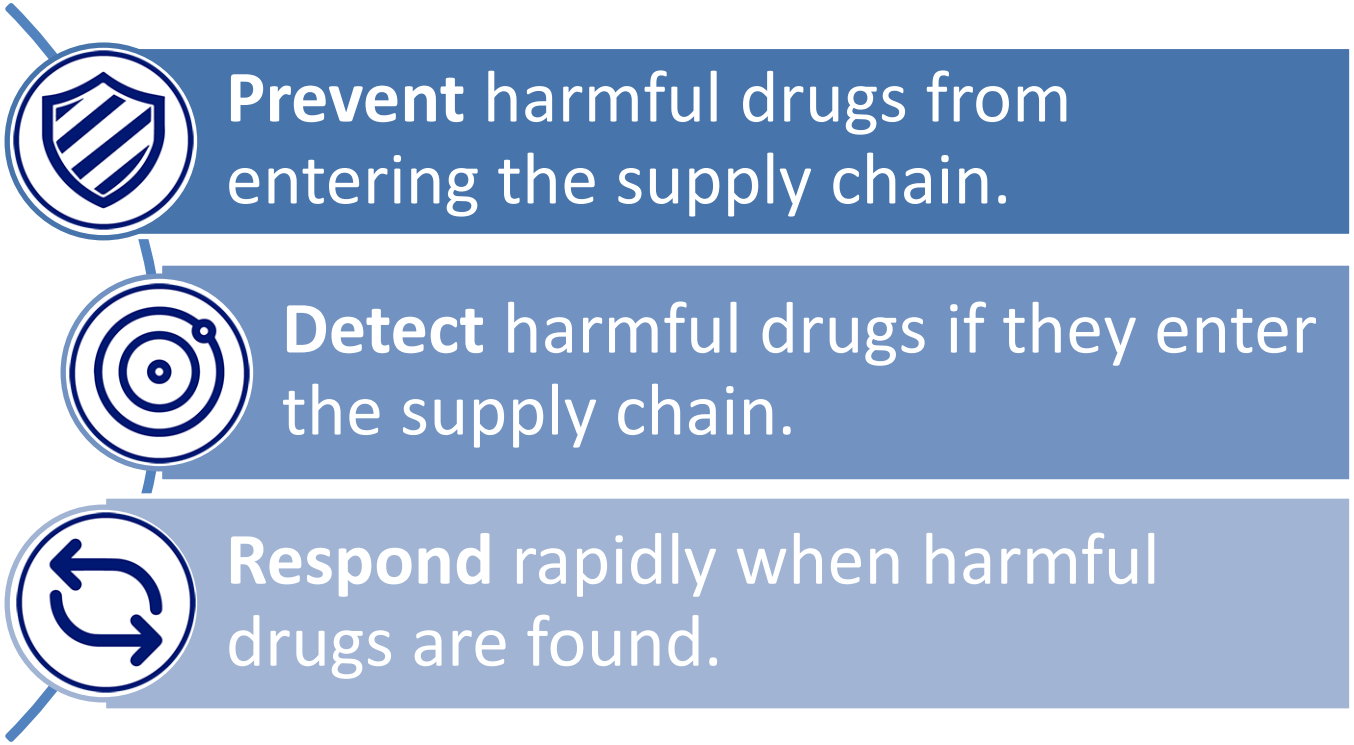
DSCSA Goals

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

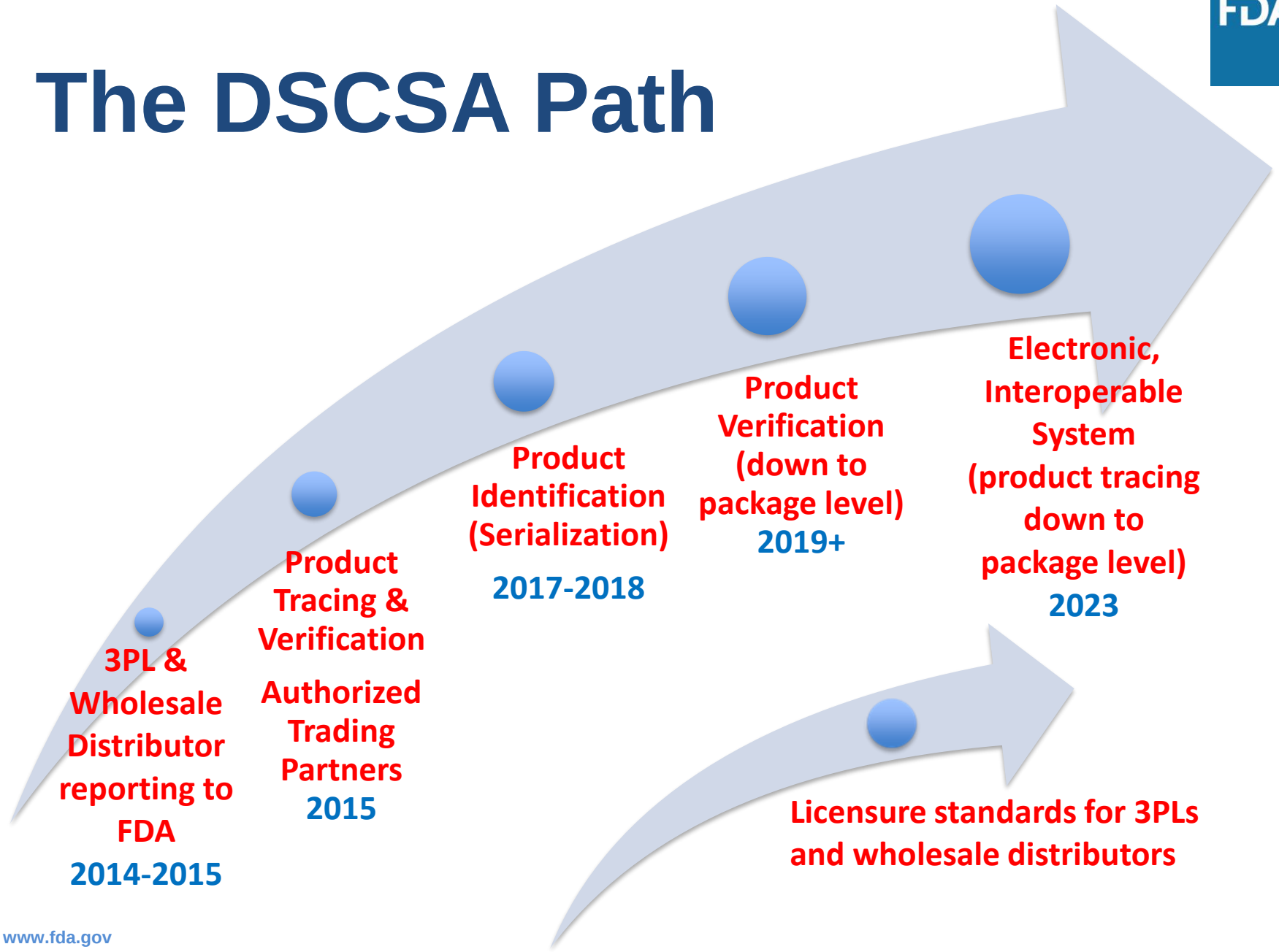
- Enable secure tracing of product at the package level
- Use product identifiers to verify product at the package level
- Enable prompt response to suspect and illegitimate products when found
- Improve efficiency of recalls

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

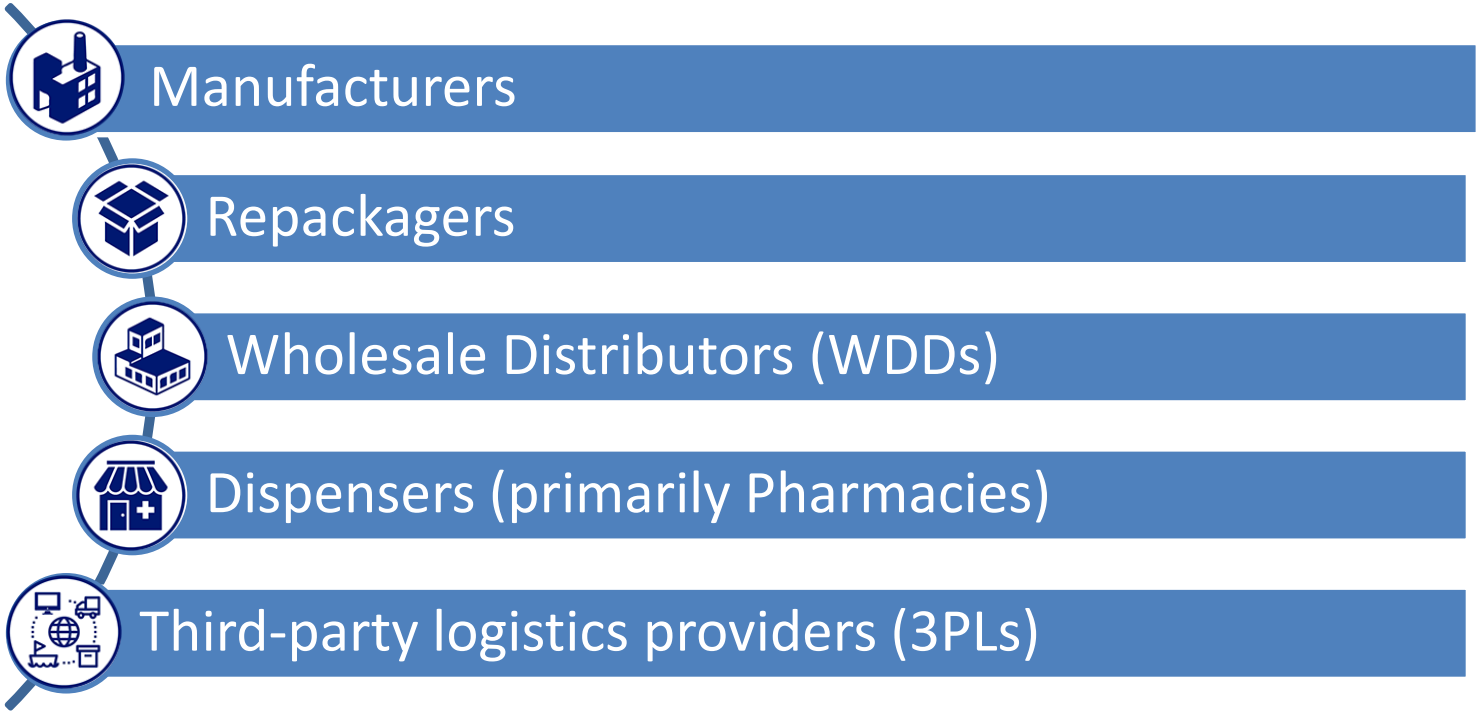
Refer to the definition for "product" in section 581(13) of the FD&C Act for specific information regarding exceptions.

Transactions

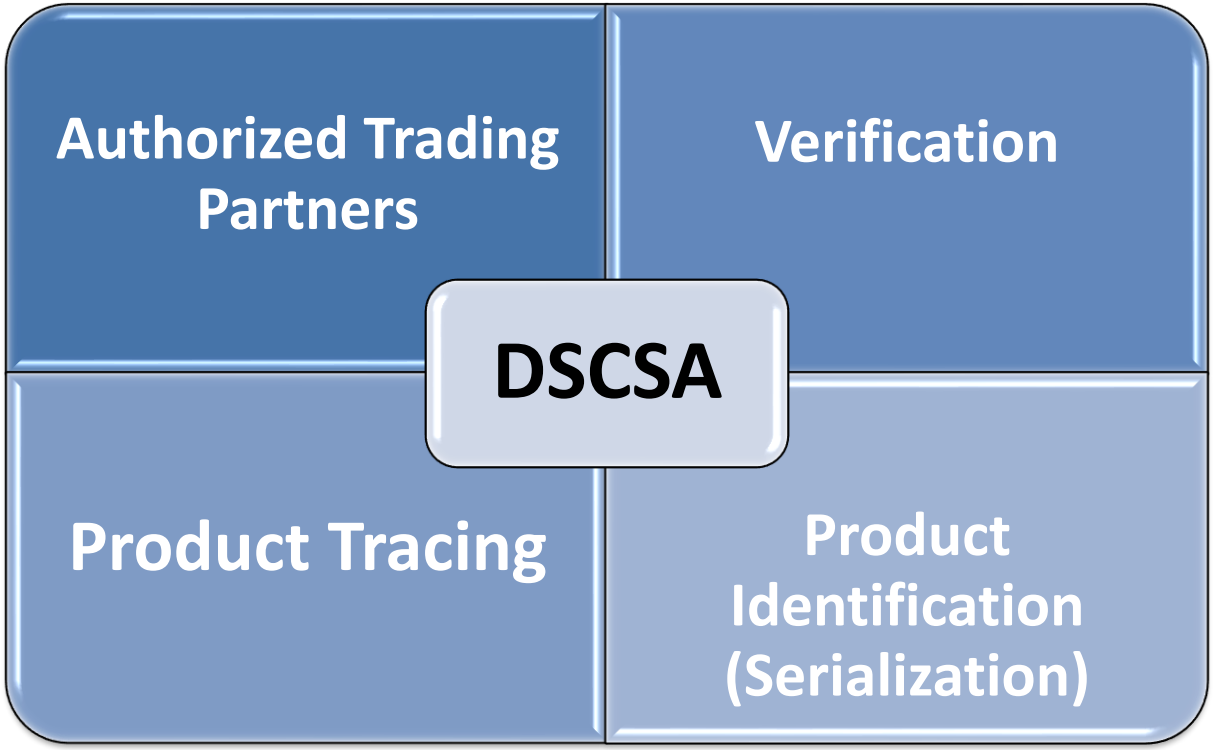
- Involve transfers of product where a *change of ownership* occurs
- Excludes:
  - Intracompany distributions
  - Distribution among hospitals under common control
  - Public health emergencies
  - Dispensed pursuant to a prescription
  - Product sample distribution
  - Blood and blood components for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



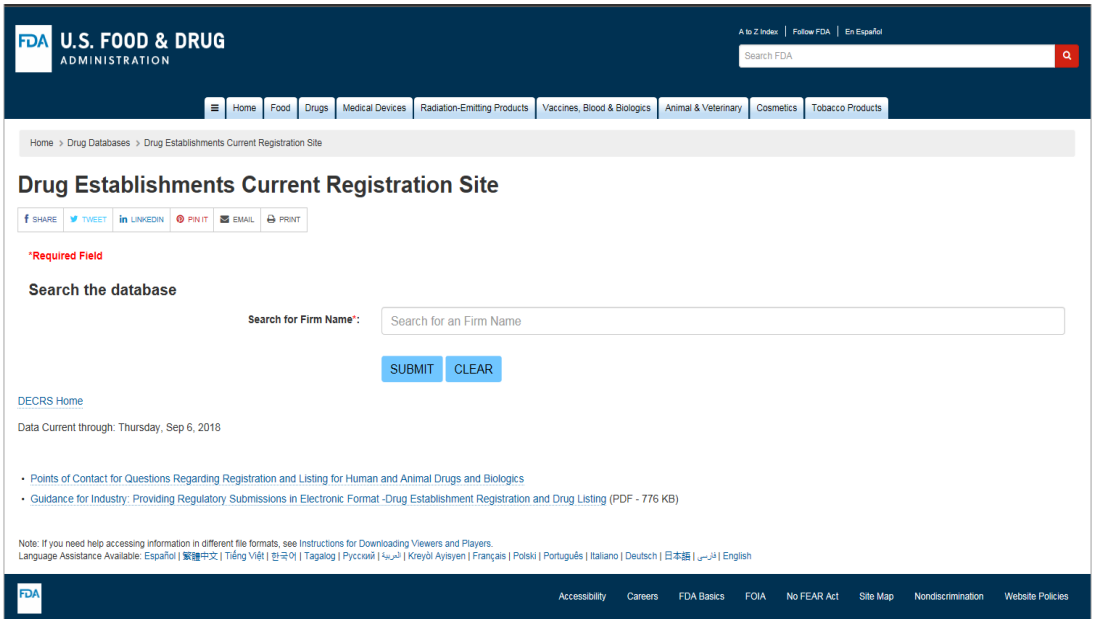
*The requirements under section 582 of the FD&C Act apply to manufacturers, repackagers, wholesale distributors, and dispensers (pharmacies).

Authorized Trading Partner Requirement

Manufacturers and Repackagers	Wholesale Distributors and 3PLs	Dispensers
• 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

Trading partners must be authorized!

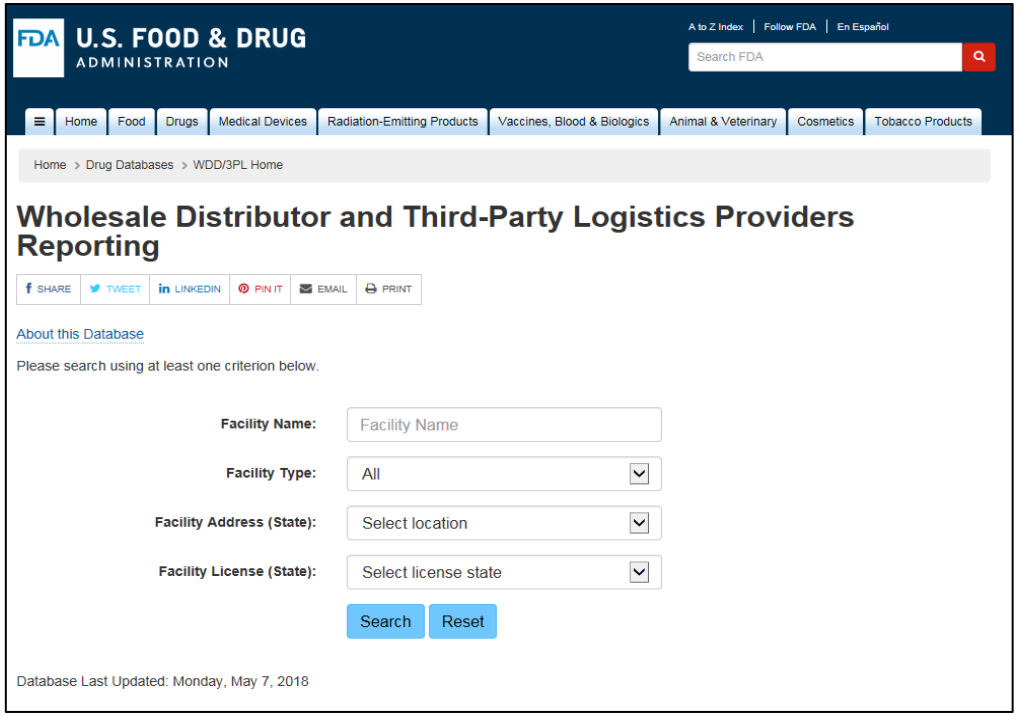
FDA's Drug Establishment Current Registration Site (DECRS)



- 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



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.

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 trans… a prescription drug to another trading partner
Respond	Respond to a request for information, in the event of a recall or … suspect or illegitimate product
Store	Store product tracing information you receive for at least 6 years
Return	Return product to the trading partner that you bought the drug from

CURRENTLY LOT-LEVEL AND IN PAPER OR ELECTRONIC FORMATS

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

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

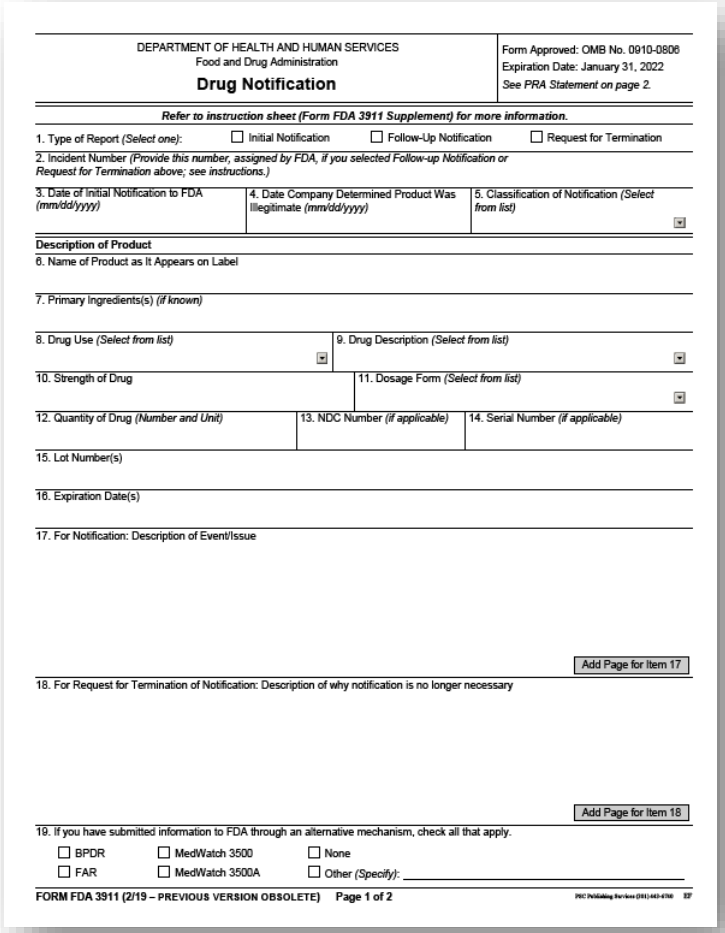
Illegitimate Product: ***credible evidence*** shows that the product is:

- 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 -- 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

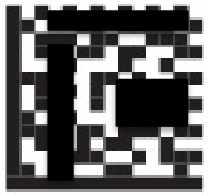
Product Identifier Requirement (Serialization)

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

DSCSA Pilot Project Program

- Explore and evaluate methods to enhance the safety and security of the drug supply chain
- Selected participants reflects the diversity of the supply chain including large and small entities from all industry sectors.
- Selection into this program should not be interpreted as FDA's position on an entity's compliance with regulatory requirements or an endorsement of a particular technology, system, or other approach used in a pilot project.

DSCSA Pilot Project Program

Estimated Timeline for Pilot Projects and Progress Reports

Effective November 27, 2023

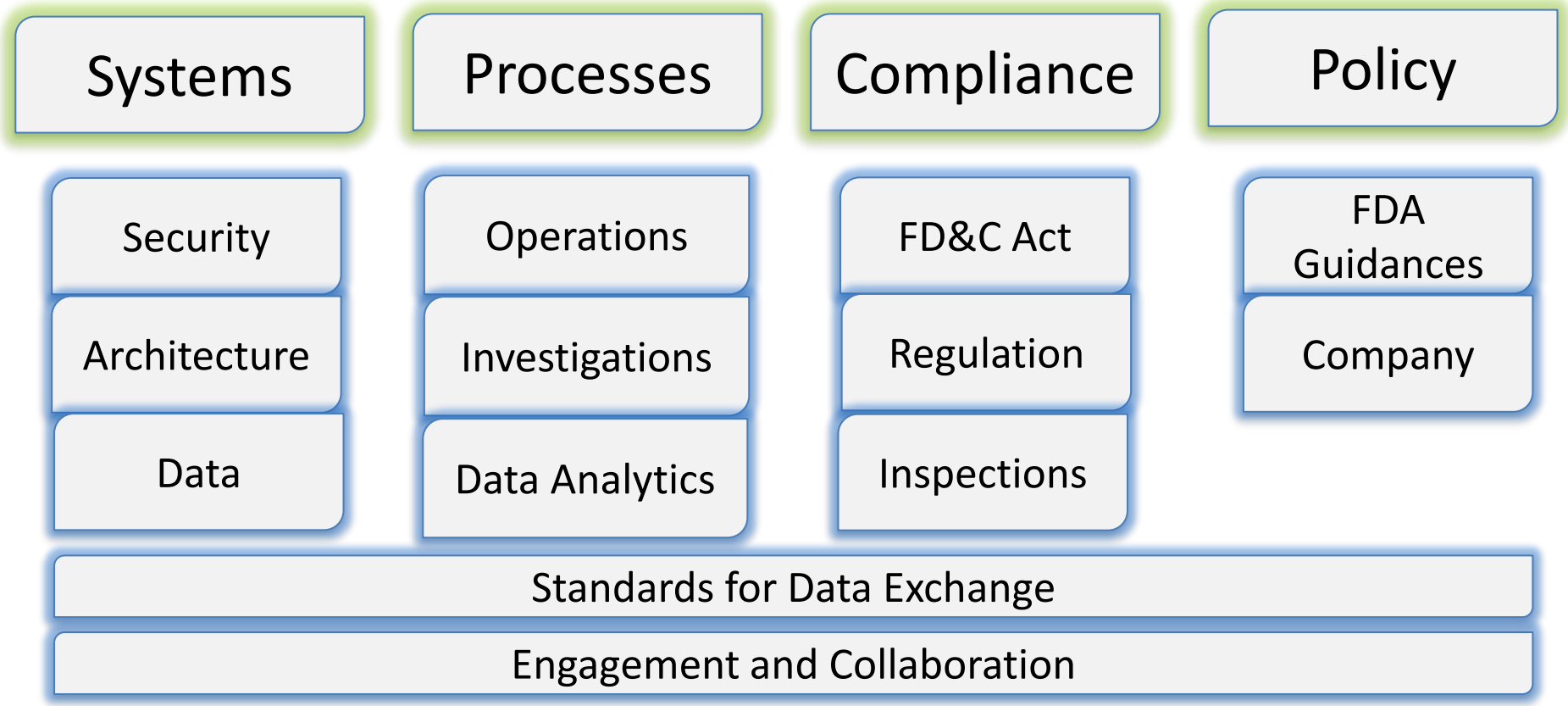
Enhanced Drug Distribution Security

Electronic

Interoperable

System across the pharmaceutical distribution supply chain

Enhanced Drug Distribution Security



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