Dispensers: What you should know about DSCSA (Drug Supply Chain Security Act)

American Pharmacists Association

November 2021

For Every Pharmacist. For All of Pharmacy.

pharmacist.com

Learning objectives

- Describe the Drug Supply Chain Security Act (DSCSA or track and trace law)
- Identify pharmacists' responsibilities under the DSCSA
- Discuss how pharmacists can protect patients from getting substandard and counterfeit drugs

Why DSCSA?

Case Study: Lipitor® US Recall

"It was the largest recall of counterfeit medicines to date in the US. Just one counterfeit case, but over 18 million Lipitor® tablets affected. In the short time from discovery to recall the fake medicines had spread to 15 US states."

TREATMENTS

FDA Warns About Fake Avastin In U.S.

February 15, 2012 · 2:40 PM ET

RICHARD KNOX

The Food and Drug Administration says counterfeit Avastin, a costly cancer drug, has made its way to doctors in the United States.

The counterfeit doesn't contain the active ingredient. Genentech, the Roche unit that makes Avastin, said Tuesday it's aware of the problem and is working with the FDA and law enforcement.

Last week, the agency sent 19 letters to cancer specialists in California, Texas and Illinois who are believed to have purchased the fake Avastin.

COMBATING COUNTERFEIT DRUGS
A Report of the Food and Drug Administration

February 2004

Pharmacy Times News Media

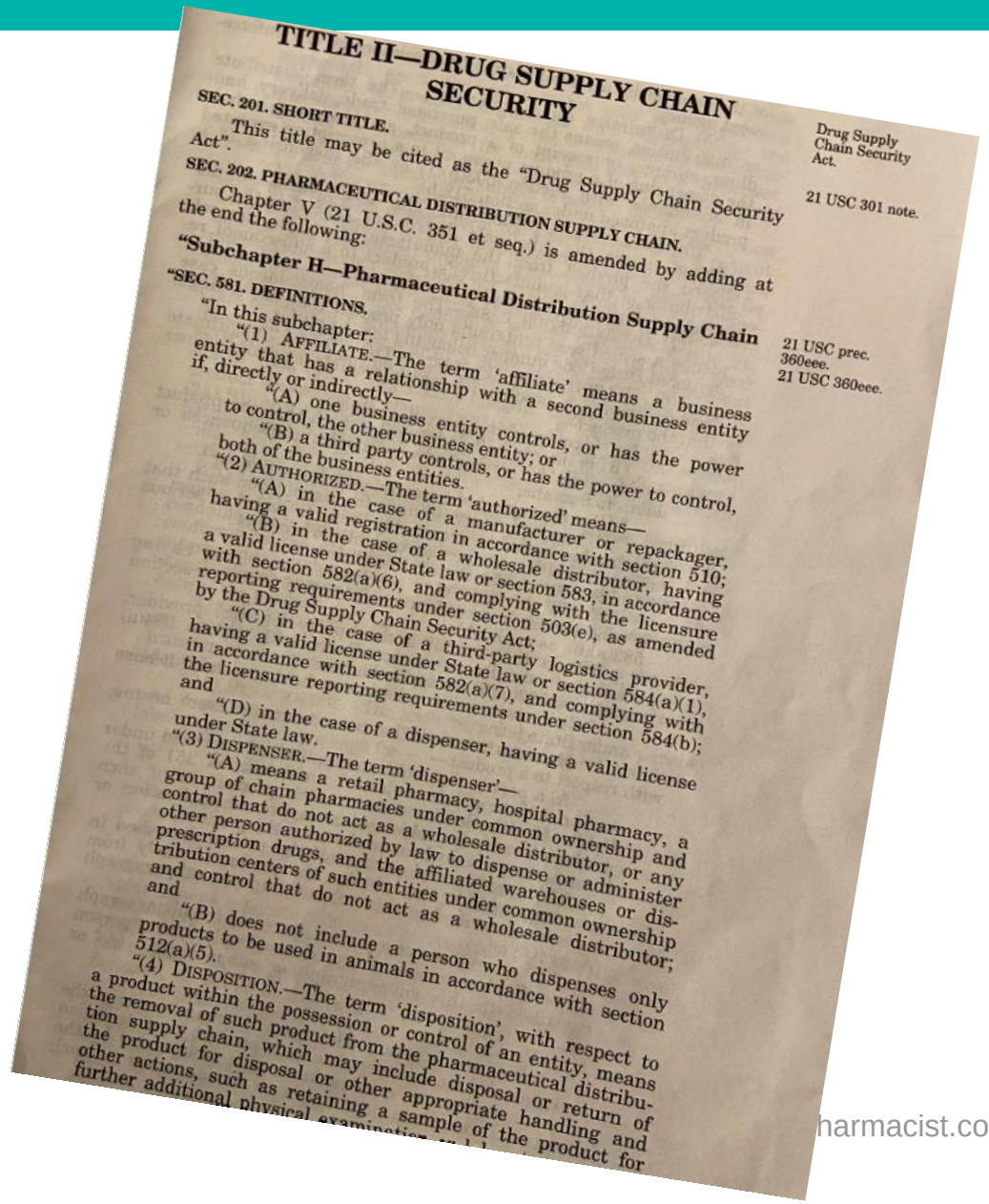
Counterfeit Drugs: A Real Cause for Alarm

December 1, 2004
Monica Holmberg, PharmD
Pharmacy Times, Volume 0,0

What is DSCSA?

Drug Quality and Security Act of 2013
(Public Law 113-54)

- Title I: Drug Compounding
  - Established 503B outsourcing facilities
- Title II: Drug Supply Chain Security
  - Product tracing
  - Wholesale distribution standards



TITLE II—DRUG SUPPLY CHAIN SECURITY

Drug Supply Chain Security Act.

SEC. 201. SHORT TITLE.

This title may be cited as the "Drug Supply Chain Security Act".

21 USC 301 note.

SEC. 202. PHARMACEUTICAL DISTRIBUTION SUPPLY CHAIN.

Chapter V (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

"Subchapter H—Pharmaceutical Distribution Supply Chain

21 USC prec. 360eee.

"SEC. 581. DEFINITIONS.

21 USC 360eee.

"In this subchapter:

"(1) AFFILIATE.—The term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly—

"(A) one business entity controls, or has the power to control, the other business entity; or

"(B) a third party controls, or has the power to control, both of the business entities.

"(2) AUTHORIZED.—The term 'authorized' means—

"(A) in the case of a manufacturer or repackager, having a valid registration in accordance with section 510;

"(B) in the case of a wholesale distributor, having a valid license under State law or section 583, in accordance with section 582(a)(6), and complying with the licensure reporting requirements under section 503(e), as amended by the Drug Supply Chain Security Act;

"(C) in the case of a third-party logistics provider, having a valid license under State law or section 584(a)(1), in accordance with section 582(a)(7), and complying with the licensure reporting requirements under section 584(b); and

"(D) in the case of a dispenser, having a valid license under State law.

"(3) DISPENSER.—The term 'dispenser'—

"(A) means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor; and

"(B) does not include a person who dispenses only products to be used in animals in accordance with section 512(a)(5).

"(4) DISPOSITION.—The term 'disposition', with respect to a product within the possession or control of an entity, means the removal of such product from the pharmaceutical distribution supply chain, which may include disposal or return of the product for disposal or other appropriate handling and other actions, such as retaining a sample of the product for further additional physical

Drug Supply Chain Security Act of 2013

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

Facilitate electronic exchange of transaction information for each sale of prescription drugs	Use product identifiers to verify product at the package level	Enable prompt response to suspect and illegitimate products when found	Improve efficiency of recalls

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

DSCSA terms

Dispenser:

- A retail pharmacy, hospital pharmacy, or a group of chain pharmacies under common ownership or control, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities.

- Excludes: –
  - if such entity acts as a wholesale distributor;
  - a person who only dispenses products used with animals.

DSCSA terms

Product:

- Prescription drug in finished dosage form for administration to a patient without further manufacturing (such as capsules, tablets, lyophilized products before reconstitution)
- Not included:
  - Blood or blood components intended for transfusion
  - Radioactive drugs/biologics
  - Imaging drugs
  - Certain IV drugs
  - Medical gas
  - Homeopathic drugs
  - Lawfully compounded drugs

Authorized Trading Partner	• Buy only from authorized trading partners with valid registration or licensure
Product Tracing	• Exchange transaction documentation
Product Verification	• Quarantine and investigate • Respond if receive notification of illegitimate product • Notify FDA if illegitimate product found • Recordkeeping
Serialization	• Product identifier in human readable and 2D bar code on all covered products • Only purchase serialized product

NOW!!

Only do business with an authorized trading partner

- Manufacturer and repackager
  - Must be registered with FDA
- Wholesalers
  - Must have valid state or federal license and report license to FDA
  - Check FDA database
- Dispensers
  - Must have valid state license

NOW!!

Have and follow processes for product tracing information

Receive
- Only accept Rx drugs with product tracing information

Provide
- Generate and provide product tracing info when you sell to another trading partner
- Not needed when dispense to a patient or sell to a pharmacy for a specific patient

Respond
- For recall or to investigate suspect or illegitimate product respond within 2 biz days

Store
- At least 6 years

Return
- Only to trading partner where you bought it

NOW!!

Know what is a suspect or illegitimate product

Looks different

Something phishy

No "Rx only"

Damaged, broken seal

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 would result in serious adverse health consequences or death to humans

Altered product info

Missing info on label

Product tracing info missing or different

Lot number or exp date don't match

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

- 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

Missing/ wrong insert

Foreign language?

NOW!!

Have and follow processes for product verification for suspect and illegitimate product

Quarantine and investigate

- Suspect prescription drugs to determine if illegitimate

Investigation

- Validate transaction information and history
- Verify lot number
- Retain sample if illegitimate

Notify

- If product is illegitimate, notify FDA (using Form FDA 3911) and trading partners you bought from and sold to, within 24 hours

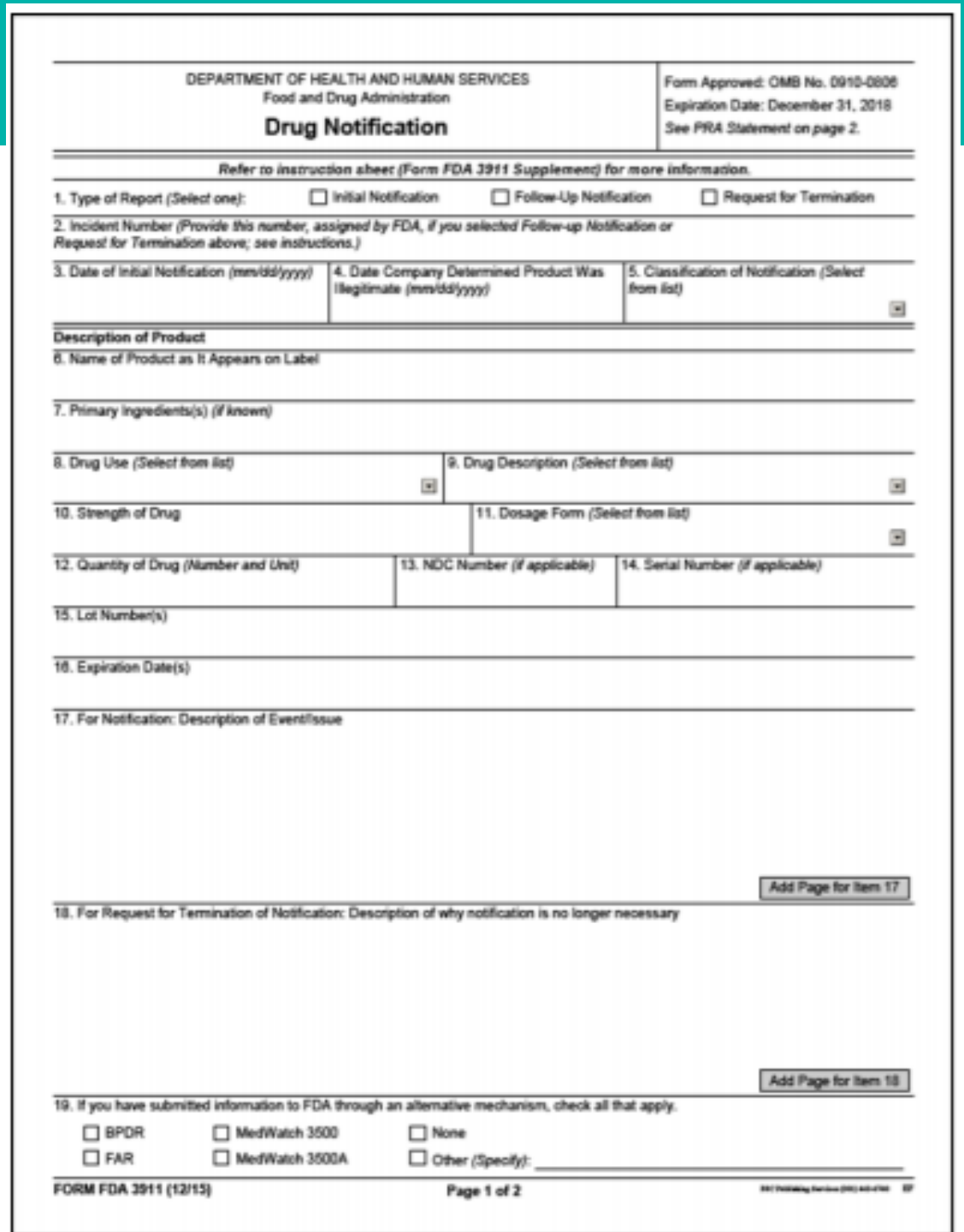
Respond

- If illegitimate, coordinate and work with manufacturer to keep drug from reaching patients

Store

- Keep records of investigation of suspect and product disposition of illegitimate product for at least 6 years

FDA Form 3911



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Drug Notification

Form Approved: OMB No. 0910-0806
Expiration Date: December 31, 2018
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 *(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 (12/15) Page 1 of 2

https://www.fda.gov/about-fda/reports-manuals-forms/forms

NOW!!

Only buy/sell product with serialized product identifier on package

- Some exceptions:
  - Not “product”
  - Grandfathered
  - Waiver/exempt
- If unsure:
  - Check product tracing information
  - Check with manufacturer, repackager, or wholesaler

Product identifier/serialization is placed on product package by manufacturer or repackager

DSCSA Timeline

(For dispensers)

Since 2015….

- Lot level tracing
- Verification of suspect/illegitimate product
- Only do business with authorized trading partners

Since 2019….

- Item level serialization begins

Since 2020....

- Dispensers can only buy serialized product
- Dispensers must verify product identifiers for certain packages of suspect products

In 2023….

- Item level tracing
- Electronic, interoperable tracing system in place

Prepare for November 27, 2023

- Be ready to exchange transaction information (with specific product identifier for each package) and transaction statements electronically
- Implement systems/processes for package-level verification, including the standardized numerical identifier
- Implement systems/processes to facilitate the gathering the information necessary to produce the transaction information and statement for each transaction going back to the manufacturer if FDA or trading partner requests for investigation
- Can enter into an agreement with a 3rd party to maintain transaction documentation

How to prepare for 2023

- Talk to your wholesaler. They likely are already planning.
- Volunteer to help or be a sounding board. FDA and private sector groups need pharmacist input and advice.
- Review FDA guidances when they are published. Do they make sense? Is it doable? Provide feedback/comment.
- Keep an eye out for FDA's small dispenser feasibility study.
- Learn more about DSCSA.
  - Check out FDA's website.
  - Check out Dispenser specific Qs and As prepared by the Pharmaceutical Distribution Security Alliance https://pdsaonline.org/wp-content/uploads/2020/10/PDSA-QA-Document-on-Dispenser-Requirements_Final-1.pdf

Why it is important to comply with DSCSA?

Because failure to comply can result in penalties: imprisonment and/or fines

SEC. 206. PENALTIES.

(a) PROHIBITED ACT.—Section 301(t) (21 U.S.C. 331(t)), is amended—

(1) by striking "or" after "the requirements of section 503(d),"; and

(2) by inserting ", failure to comply with the requirements under section 582, the failure to comply with the requirements under section 584, as applicable," after "in violation of section 503(e)".

(b) MISBRANDING.—Section 502 (21 U.S.C. 352), as amended by section 103, is further amended by adding at the end the following:

Check out FDA's DSCSA website

https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa

Be vigilant.

Be diligent.

Be ready.

For our patients.

Thank you!!!

ILISA BG BERNSTEIN, PharmD, JD, FAPhA
Senior Vice President, Pharmacy Practice and Government Affairs
ibernstein@aphanet.org

KARIN BOLTE, JD
Director, Health Policy
kbolte@aphanet.org