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## Track & Trace

2015 Changes to the Food, Drug,  
and Cosmetic Act:  
*The Drug Supply Chain Security Act*

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PRESIDENT & FOUNDER  
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## The DSCSA: TRACK & TRACE

- ▶ **The Drug Supply Chain Security Act (DSCSA)** was signed into law in November, 2013
- ▶ DSCSA is a section of the FDA Food, Drug, and Cosmetic Act (FD&C Act)
- ▶ Sections 581 and 582 of the FD&C Act are Section 202 of the DSCSA, otherwise known as **Track and Trace**
- ▶ The DSCSA went into effect on January 1, 2015 for manufacturers, repackagers, and wholesalers, and July 1, 2015 for dispensers

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## Why we need the DSCSA

- ▶ The purpose of the DSCSA is to identify and remove potentially harmful pharmaceuticals from the market
- ▶ Primarily, counterfeit drugs

"But counterfeit drugs aren't a problem for my ASC..."

Are you sure?

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## The Effect of Counterfeit Drugs

- ▶ Counterfeit drugs can come down through the Drug Supply Chain
- ▶ In some cases, there are many steps/ parties in the supply chain
- ▶ Pedigree Papers can be counterfeited
- ▶ Counterfeit Drugs may be weaker, ineffective, or contain unsafe additives meant to supplement siphoned ingredients

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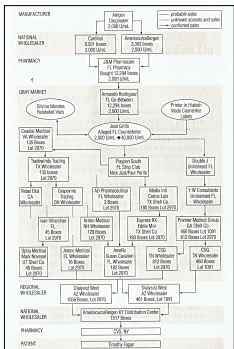
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## The Epogen Trail to Timothy Fagan



- ▶ 16 year old Timothy Fagan received liver transplant
- ▶ Prescribed Epogen for anemia
  - ▶ SDV. 40,000 U/mL dose, was \$470
  - ▶ Tim experienced severe reactions such as severe cramping, convulsions, and seizing, none of which were known side effects
  - ▶ Drug did not have desired effect
- ▶ The Epogen Tim was taking had been counterfeit
- ▶ The drug had a weaker strength AND was potentially supplemented with unknown substances

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**Pedigree Papers**



- ▶ Pedigree Papers were the first efforts to reduce the risk of counterfeit drugs
- ▶ Information includes: drug's quantity, dosage, strength, and lot number; and the names and addresses of the manufacturer, wholesaler, and purchaser
- ▶ These documents became more easily counterfeited and did not require verification by the end purchaser

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**Track & Trace: The Basics**



- ▶ All **trade partners** are required to pass along certain information about prescription drugs, upon the transfer or purchase of the drug, to the subsequent owner:
  - ▶ Documents
    - ▶ Transaction Statement
    - ▶ Transaction History
    - ▶ Transaction Information
  - ▶ All three documents may be located on a single page

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**Track & Trace: The Basics**



- ▶ All **trade partners** are required to maintain this information for 6 years
  - ▶ Electronic
  - ▶ Hard Copy
- ▶ Trade Partners are required to *verify the information provided* in the transaction documents before taking ownership of the drug OR selling the drug
- ▶ Transaction Documents will look different depending on the company but will ALWAYS contain the same information

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Transaction Documents



**Transaction Information (TI)**

- Proprietary/ established drug name
- Strength & dosage form
- National Drug Code number
- 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
- Business name and address of the person from whom and to whom ownership is being transferred

**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
- 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
- Did not knowingly alter the transaction history

**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.

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What about Recalls?



- ▶ The transaction statement, information, and history are required to be kept on file for 6 years by trade partners
- ▶ The LOT NUMBER is **not** required to be kept on file at the ASC or in a patient's chart
- ▶ In the case of a recall you will be contacted by your medication supplier with instructions
  - ▶ When in doubt, call your consultant pharmacist!

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Track & Trace: Who is affected?



- ▶ All **trade partners** involved in the transmission of prescription drugs must comply with the DSCSA
- ▶ **Trade Partners** include:
  - ▶ Manufacturer
  - ▶ Distributor
  - ▶ Wholesaler
  - ▶ Dispensers: 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

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**Track & Trace in the ASC**



- ▶ ASCs ARE considered trade partners as dispensers.

HOWEVER, the following exemption applies:

- ▶ Sec 582.d.5 "EXCEPTION.—Notwithstanding any other provision of law, the requirements under paragraphs (1) and (4) shall not apply to licensed health care practitioners authorized to prescribe or administer medication under State law or other licensed individuals under the supervision or direction of such practitioners who dispense or administer product in the usual course of professional practice."
- ▶ This exception refers to tracking (1) and verification (4) portions of the law

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**Track & Trace in the ASC**



- ▶ Trade partners are required to provide you with the transaction history, transaction statement, and transaction information **BUT** ASCs are not obligated to verify these documents before taking ownership of the drug
- ▶ ASCs are not obligated to maintain these documents for 6 years
- ▶ If an ASC transfers or sell a prescription drug to another health care entity with the purpose of administration to a patient, you must deliver the transaction documents with the drug
  - ▶ Transaction documents DO NOT need to be provided to drug destruction companies such as a reverse distributor
  - ▶ Transaction documents DO NOT need to be provided to patients

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**Track & Trace in the ASC**  
Requirements at the Ambulatory Level Cont'd



- ▶ If you do not receive transaction documents upon receipt of drug, request them to ensure legitimacy of the medication
- ▶ ASCs are only allowed to trade with authorized trading partners
- ▶ Authorized means:
  - ▶ Manufacturers and Repackagers: require valid registration with the FDA
  - ▶ Wholesale Distributors: require a valid state or federal license
  - ▶ Dispensers: require a valid state license

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**Track & Trace in the ASC**  
Exemptions at the Ambulatory Level



- ▶ NOT required to maintain transaction history, transaction statements, and transaction information on site for 6 years
- ▶ NOT required to verify legitimacy of drug before taking ownership
- ▶ **HOWEVER:** We recommend you STILL obtain these documents upon receipt of drug
  - ▶ Ensures that Trade Partner is a legitimate member of the drug supply chain
  - ▶ Helps to ensure that you are NOT receiving counterfeit drugs

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**Internal Track & Trace Policy**



- ▶ Add a Track & Trace Policy to the ASC's policy book
- ▶ Include the ASC's protocol for receipt and storage of the transaction documents, if you plan to store them

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**The Future of Track & Trace**

- ▶ Product Serialization (2017/ 2018/ 2019/ 2020):
  - ▶ Tiered start date depending on type of Trade Partner
  - ▶ Unique product identifier on prescription drugs
- ▶ 2D barcode includes:
  - ▶ NDC
  - ▶ Serial Number
  - ▶ Lot Number
  - ▶ Expiration Date
- ▶ 2023: Enhanced Verification System

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Questions??

Email your questions regarding today's content to:  
[info@pss4asc.com](mailto:info@pss4asc.com)



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  - ▶ Or call us! (855) 777-4272



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Mark your calendars...

**PROGRESSIVE HALF TIME**  
**Monday, October 26, 2015**  
11AM PT/2PM ET

**SURVEY PREPARATION**  
Crissy Benze, RN, BSN

**\$75**  
**FREE for eSupport members!!**



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Mark your calendars...

*Progressive Huddle*  
**Monday, November 17, 2015**  
11AM PT/2PM ET

**ANNUAL SURVEY WATCH REPORT**  
Leanne Gallegos, RN, BSN





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