UI Health

Do you know where your medications are coming from? The FDA wants to know!

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Conflict of Interest

- The speakers has no actual or potential conflict of interest in relation to this presentation

Pre-Test Question #1

Which of the following statements are correct?

A. Drug Supply Chain Act (DSCSA) will enhance FDA's ability to protect consumers from drugs that may be counterfeit, stolen, contaminated or harmful.
B. The will be no penalties if institutions are not compliant with DSCSA in the future
C. DSCSA will improve detection and removal of potentially dangerous drugs from the drug supply chain
D. A & C

Pre-Test Question #2

What year will the DSCSA require unit level traceability?

A. 2020
B. 2023
C. 2026
D. 2030

Pre-Test Question #3

Which of the following is not a goal of the DSCSA

A. Facilitate efficient drug product recalls
B. Facilitate the exchange of information at individual package level
C. Facilitate pricing transparency at national level
D. Enhance detection and notification of illegitimate products in the drug supply chain

Pre-Test Question #4

An entity that dispenses greater than 5% of the dollar value of the pharmacy's annual prescription drug sales is considered a dispenser?

A. True
B. False

Learning Objectives

- Explain the Drug Supply Chain Security Act (DSCSA)
- Outline the implementation process for a track and trace system at one facility
- Review how a track and trace system is used at one facility
- Describe future considerations regarding DSCSA

Drug Quality & Security Act (DQSA)
Nov 27, 2013

- Title II – **Drug Supply Chain Security Act (DSCSA)**
  - Outlines steps to build **an electronic, interoperable system** to identify and trace prescription drugs distributed in the USA
- **Objective**
  - Enhance FDA's ability to **protect consumers from drugs that may be counterfeit, stolen, contaminated, or harmful**
  - Improve detection and removal of potentially dangerous drugs from the drug supply chain
  - Penalties if fail to comply

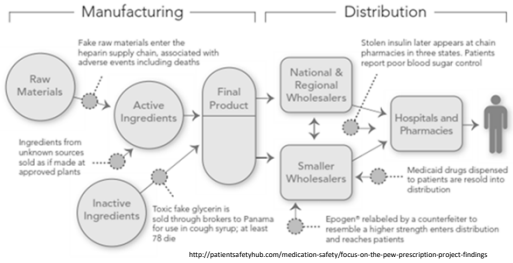
Goals of DSCSA

- End goal in Nov 2023
  - Facilitate **exchange of information** at **individual package label**
  - Verification of **legitimacy** of the drug product identifier
  - Enhance **detection and notification** of **illegitimate products** in the drug supply chain
  - Facilitate efficient drug product **recalls**

Track where the drug has been throughout the drug supply chain
(TRACEABILITY)

Why this is important?

Vulnerabilities in the Drug Supply Chain



http://patientsafetyhub.com/medication-safety/focus-on-the-pew-prescription-project-findings

Suspect vs Illegitimate

- **Suspect product**
  - Potentially **counterfeit, diverted or stolen**
  - Potentially **intentionally adulterated**
  - Potentially **fraudulent transaction**
  - Potentially **unfit for distribution**

Results in serious adverse health consequences or death

- **Illegitimate product**
  - All of the above, but replace "potentially" with "creditable evidence showing"

What is considered a Product?

Products	Non-Products
• Capsules • Tablets • Lyophilized products before reconstitution	• Blood or blood components intended for transfusion • Radioactive drugs or biologicals • Certain IV drugs • Imaging drugs • Medical gases • Homeopathic drugs • Compounded drugs

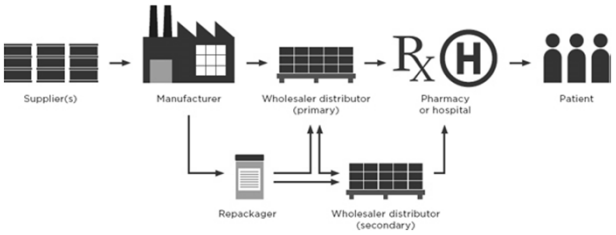
Title I: Compounding Quality Act (CQA)

Who is involved?

Authorized Trading partners

Manufacturer	• Licensed entity that manufactures the product	Valid **FDA registration**
Repackager	• Licensed establishment that repacks and relabels product for further sale or distribution without further transaction	
Wholesale distributer	• Distribution to entity/person other than the patient • Distribute to hospital or other health entities	Valid **State or Federal license** and **compliance with reporting requirements**
Third party logistics provider (3PL)	• Licensed entity that provide storage and logistical operations related to product distribution; no ownership of product	
Dispenser	• Community, chain or hospital pharmacies • No further transactions	Valid **State license**

Drug Supply Chain



https://www.nap.edu/read/18272/chapter/7#198

Wholesale Distributer vs Dispenser

- Per the DSCSA, 'transaction' does not include "the distribution of minimal quantities of product by a licensed retail pharmacy to a licensed practitioner for office use"
  - **Minimal quantities** defined as "not exceeding 5% of the dollar value of the pharmacy's annual prescription drug sales
    - **Five Percent Rule**
      - Dispense > 5%: wholesale distributer
      - Dispense < 5%: dispenser

Key Provisions of DSCSA

- Product tracing (TI + TS + TH = T3)
  - FDA Guidance Document: *Product Tracing Requirements – Compliance Policy*
- Product identification/serialization
- Product verification (Detect, Notify & Respond)
  - FDA Guidance Document: *Identification of Suspect Product and Notification*
- Wholesaler & Third-party logistics provider licensing

Product Tracing (T3)

Who | What | Where | When | Why

Exchange of transaction documentation (paper or electronic) must contain:

- **(TI) <u>Transaction Information</u>**
  - **Name** of the product
  - **Strength** and **dosage form**
  - **National Drug Code (NDC)**
  - **Container size** and quantity
  - **Lot number**
  - **Expiration date**
  - **Transaction date**
  - **Shipment date** (if >24h after transaction date)
  - **Wholesaler contract info**
  - **Transfer to and from**
- **(TS) <u>Transaction Statement</u>**
  - DSCSA authorized entity
    - **Transferring product to…**
    - **Receiving product** from…
  - **Received TI and a TS**
  - Have systems and processes in place to **comply with verification requirements** under the law
  - **<u>DID NOT</u>** knowingly
    - Ship a **suspect or illegitimate product**;
    - Provide **false TI**;
    - **Alter the TH**
- **(TH) <u>Transaction History</u>**
  - Transaction information **for each prior transaction** going back to the manufacturer of the product

T3 Example

Product Information

NDC	Product Name	Strength	Dosage Form	Container Size	Lot Number	Expiration Date
55292081155	DACTINOMYCIN	0.5 MG	VIAL	1 EACH	W051247	31 May 2019

Transaction Information - RECORDATI RARE DISEASES INC to AmerisourceBergen -

TRANSACTION DATE	--	TRANSFER FROM	RECORDATI RARE DISEASES INC 100 CORPORATE DRIVE LEBANON, NJ 08833
SHIPMENT DATE	--	TRANSFER TO	AmerisourceBergen 1300 Morris Drive Chesterbrook, PA 19087
QUANTITY SHIPPED	0		

Transaction Information - AmerisourceBergen to UNIV OF ILLINOIS HOSP PHARMACY - 10 Aug 2017

TRANSACTION DATE	10 Aug 2017	TRANSFER FROM	AmerisourceBergen 1300 Morris Drive Chesterbrook, PA 19087
SHIPMENT DATE	09 Aug 2017	TRANSFER TO	UNIV OF ILLINOIS HOSP PHARMACY 1740 W TAYLOR, DELIVER TO LOADING DOCK CHICAGO, IL 60612
QUANTITY SHIPPED	2		
TRANSACTION IDENTIFIER	INV 1191671434 1 PO 00092017		
TRANSACTION STATEMENT	AmerisourceBergen has complied with each applicable subsection of FDCA Sec. 581(27)(A)-(G)		
DIRECT PURCHASE STATEMENT	Product was purchased directly from the manufacturer, manufacturer's exclusive distributor or repackager who purchased directly from a manufacturer.		

Exchange Information

HISTORY RECEIVED	10 Aug 2017 11:02 AM GMT by Info Exchange
QUANTITY RECEIVED	0

T3 Exemptions

- **Non-products** and product samples
- Medical devices and medical convenience kits containing drug products
- **Intracompany transfers**
- Sales from dispenser to dispenser for patient-specific needs
- **Distribution among hospitals or health care entities under common control**
- Distribution for public health emergencies (excludes drug shortages)
- Distribution to nonprofit affiliate of a charitable organization
- Distribution of *minimal* quantities by licensed retail pharmacy to licensed practitioner for office use
- **Products transferred pursuant to a patient-specific prescription**

Product Identification/serialization

- Tracking by unit-package level
- Unique product identifier
  - **2D Bar Code** (data carrier)
    - NDC
    - SNI
    - Expiration Date
    - Lot Number

NDC: 59148 011 13
SN: 100000000001
EXP: AUG 22 2015
Lot: AB100613

VS

Linear Barcode

Product Verification

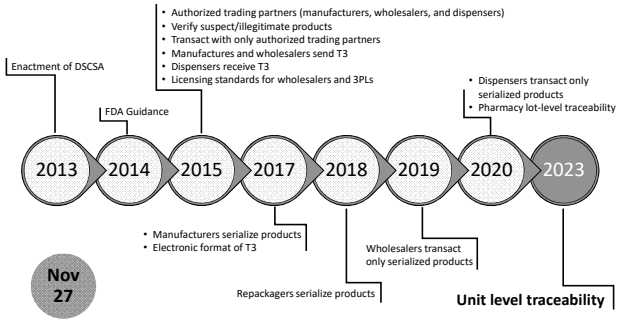
Detect, Notify & Respond

- Respond to verification request about *suspect* product(s)
- **Quarantine** and **investigate** suspect product(s) to determine if *illegitimate* product(s)
  - Validate T3 data
  - Verify product identifiers of at least 3 packages or 10% of suspect products
- **Determine** if product is illegitimate
- **Notify** trading partners and FDA of illegitimate product(s) within 24 hours
  - Use FDA Form 3911 for notification and for termination of notification
- **Respond** to notifications of illegitimate product(s)
- **Recordkeeping** (at least 6 years)

Licensing Standards: To combat the grey market

- Wholesale distributer
- Third-party logistics provider (3PL)

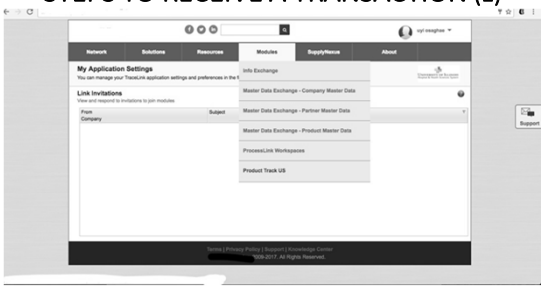
- Must report information **annually to the FDA**
  - FDA's CDER Direct Electronic Submissions Portal
- Information made **available publically**
  - The Wholesale Distributor and Third-Party Logistics Provider Reporting Database



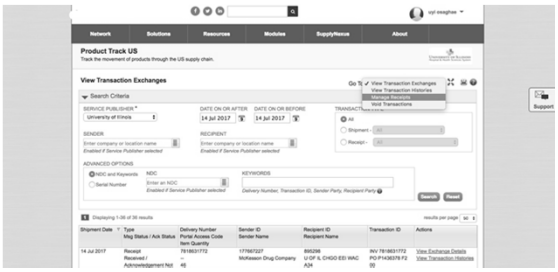
Timeline of Project

• Initial Discussions of DSCSA	January 2016
• Contract with Tracelink	July 2016
• Kickoff Meeting	September 2016
• Documentation Submissions	November 2016
• Primary Wholesaler EDI Feeds	December 2016 – March 2017
• 5% Rule (Wholesaler vs Distributor)	April 2017 – May 2017
• Implementation	June 2017 –July 2017

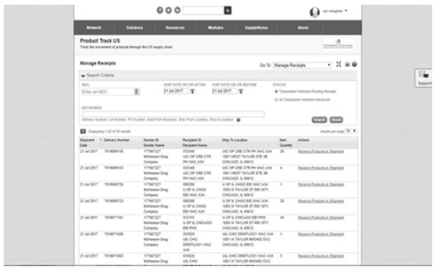
STEPS TO RECEIVE A TRANSACTION (1)



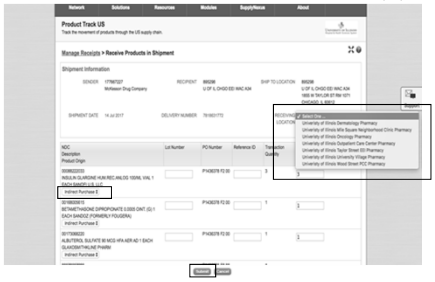
RECEIVING A TRANSACTION (2)



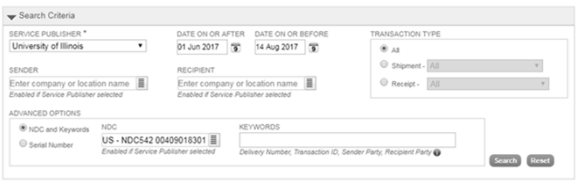
RECEIVING A TRANSACTION (3)



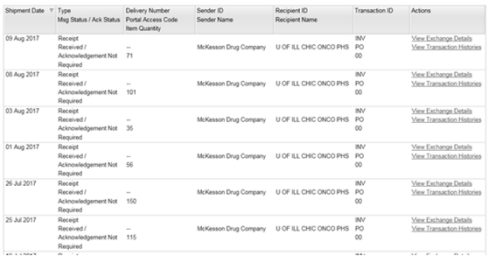
RECEIVING A TRANSACTION (4)



Auditing a Product



Found Orders

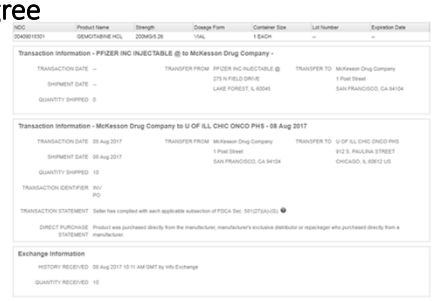


Shipment Date	Type Msg Status / Ack Status	Delivery Number Portal Access Code Item Quantity	Sender ID Sender Name	Recipient ID Recipient Name	Transaction ID	Actions
09 Aug 2017	Receipt Received / Acknowledgement Not Required	-- 71	McKesson Drug Company	U OF ILL CHIC ONCO PHS	INV PO 00	View Exchange Details View Transaction Histories
08 Aug 2017	Receipt Received / Acknowledgement Not Required	-- 101	McKesson Drug Company	U OF ILL CHIC ONCO PHS	INV PO 00	View Exchange Details View Transaction Histories
03 Aug 2017	Receipt Received / Acknowledgement Not Required	-- 35	McKesson Drug Company	U OF ILL CHIC ONCO PHS	INV PO 00	View Exchange Details View Transaction Histories
01 Aug 2017	Receipt Received / Acknowledgement Not Required	-- 56	McKesson Drug Company	U OF ILL CHIC ONCO PHS	INV PO 00	View Exchange Details View Transaction Histories
26 Jul 2017	Receipt Received / Acknowledgement Not Required	-- 150	McKesson Drug Company	U OF ILL CHIC ONCO PHS	INV PO 00	View Exchange Details View Transaction Histories
25 Jul 2017	Receipt Received / Acknowledgement Not Required	-- 115	McKesson Drug Company	U OF ILL CHIC ONCO PHS	INV PO 00	View Exchange Details View Transaction Histories

Order Line Items

Transaction Date	Transaction Type Document Status	Sender ID Sender Name	Recipient ID Recipient Name	NDC Description	Lot Number Expiration Date	Quantity	Transaction ID
08 Aug 2017	Receipt Active	McKesson Drug Company	U OF ILL CHIC ONCO PHS	00409018301 GEMCITABINE HCL 200MG/5.26 VIAL	-- --	10	DEL INVOICE
08 Aug 2017	Receipt Active	McKesson Drug Company	U OF ILL CHIC ONCO PHS	47335036141 DECITABINE 50 MG VIAL	-- --	6	DEL INVOICE
08 Aug 2017	Receipt Active	McKesson Drug Company	U OF ILL CHIC ONCO PHS	63323017260 CARBOPLATIN 10 MG/ML VIAL	-- --	6	DEL INVOICE 7823000267
08 Aug 2017	Receipt Active	McKesson Drug Company	U OF ILL CHIC ONCO PHS	25021032251 CARBOPLATIN 10 MG/ML VIAL	-- --	1	DEL INVOICE
08 Aug 2017	Receipt Active	McKesson Drug Company	U OF ILL CHIC ONCO PHS	63323017260 CARBOPLATIN 10 MG/ML VIAL	-- --	6	DEL INVOICE
08 Aug 2017	Receipt Active	McKesson Drug Company	U OF ILL CHIC ONCO PHS	62856079701 PALONOSETRON HCL 0.25MG/5ML VIAL	-- --	4	DEL INVOICE
08 Aug 2017	Receipt Active	McKesson Drug Company	U OF ILL CHIC ONCO PHS	00074334603 LEUPROLIDE ACETATE 22.5 MG SYRINGEKIT	-- --	3	DEL INVOICE 7823000267
08 Aug 2017	Receipt			AMI72013AO	--	10	DEL

Pedigree



NDC	Product Name	Strength	Dosage Form	Container Size	Lot Number	Expiration Date
00409018301	GEMCITABINE HCL	200MG/5.26	VIAL	1 EACH	--	--

Transaction Information - PFIZER INC INJECTABLE @ to McKesson Drug Company -

TRANSACTION DATE --
SHIPMENT DATE --
QUANTITY SHIPPED 0
TRANSFER FROM PFIZER INC INJECTABLE @ 235 N FIELD DRIVE LAKE FOREST, IL 60045
TRANSFER TO McKesson Drug Company 1 Post Street SAN FRANCISCO, CA 94104

Transaction Information - McKesson Drug Company to U OF ILL CHIC ONCO PHS - 08 Aug 2017

TRANSACTION DATE 08 Aug 2017
SHIPMENT DATE 08 Aug 2017
QUANTITY SHIPPED 10
TRANSACTION IDENTIFIER INV PO
TRANSACTION STATEMENT Seller has complied with each applicable subsection of FDCA Sec. 581(27)(A)-(G).
DIRECT PURCHASE STATEMENT Product was purchased directly from the manufacturer, manufacturer's exclusive distributor or repackager who purchased directly from a manufacturer.
TRANSFER FROM McKesson Drug Company 1 Post Street SAN FRANCISCO, CA 94104
TRANSFER TO U OF ILL CHIC ONCO PHS 912 S. PAULINA STREET CHICAGO, IL 60612 US

Exchange Information

HISTORY RECEIVED 08 Aug 2017 10:11 AM GMT by Info Exchange
QUANTITY RECEIVED 10

Order Information

Transaction Information

PROCESSLINK OR SERVICE	University of Illinois Product Track US	SENDER	McKesson
BUSINESS PROCESS	Product Track US	RECIPIENT	University of Illinois
TRANSACTION TYPE	Received Transaction History	TRANSACTION ID	
INPUT FILE NAME	mhosh744935-1.SAVSQ3	INPUT FILE FORMAT	X12
CANONICAL FILE NAME	mhosh744935-1.SAVSQ3.47975q8Tx	CANONICAL FILE FORMAT	X12

EDI Source Files

```
YNQ**Y***Seller has complied with each applicable subsection of FDCA Sec. 581(27)(A)-(G).***99*TS~
YNQ**Y***As indicated below, product was purchased directly from the manufacturer, manufacturer's exclusive
HL*2*1*O~
PRF*P1436390  1A    00***20170808~
REF*IV*7823000267~
DTM*003*20170808~
HL*3*2*P~
MAN*GM*00000109394445182804~
HL*4*3*I~
LIN*2*ND*62856079701*UP*362856797016~
SN1**4*EA****AC~
PID*F****ALOXI SDV 0.25MG 5ML        VL~
N1*MF*EISAI INC*92*NOTAVAIL~
N3*2260 OUTER LOOP ROAD~
N4*LOUISVILLE*KY*40219~
YNQ**Y*****99*DIR~
HL*5*3*I~
```

Upcoming from DSCSA (1)

Guidance to be provided by the FDA (Date TBD)

- **Waivers, Exceptions, Exemptions**
  - Waivers due to undue economic hardships or emergency medical reasons
  - Exceptions related to product identifiers if package is unable to accommodate a label with sufficient space
- **Grandfathering**
  - Define under what circumstances would a product without a product identifier but is in the supply chain at time of the effective date to be exempted from requirements

Upcoming from DSCSA (2)

Guidance to be provided by the FDA (Date TBD)

- 340b contract pharmacies
- Investigational drugs
- Specialty pharmacy drugs to be administered by provider

Break out groups: Discussion Time!

Post-Test Question #1

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A. True
B. False

References

1. FDA Drug Supply Chain Security Act (DSCSA). Available at: https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm. Accessed Aug 1, 2017.
2. FDA Title II of the Drug Supply Chain Security Act. Available at: http://www.fda.gov/drugs/drugsafety/drugintegrityandsupplychainsecurity/drugsupplychainse curityact/ucm376829.htm. Accessed Aug 1, 2017.
3. FDA Drug Supply Chain Security Act (DSCSA) Implementation Plan: Available at: http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChain SecurityAct/ucm382022.htm. Accessed Aug 1, 2017.
4. FDA: Are you ready for the Drug Supply Chain Security Act? Available at: https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm427033.htm Accessed Aug 1, 2017.
5. FDA DSCSA Implementation: Identification of Suspect Product and Notification – Guidance for Industry . Available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM400470.pdf. Accessed Aug 1, 2017.
6. FDA DSCSA Implementation: Product Tracing Requirements – Compliance Policy – Guidance for Industry. Available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM427867.pdf. Accessed Aug 1, 2017.