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THE STATE UNIVERSITY OF NEW JERSEY

The History and Implications of The Drug Supply Chain Security Act

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Disclosure Declaration

- Speakers have no disclosures to make

Learning Objectives (Pharmacists)

- Explain the history of the Drug Supply Chain Security Act and the new requirements imposed by the Act
- Define key terms, including pedigree, Drug Supply Chain Integrity, and product tracing
- Describe the gray market that has emerged and its meaning in the legal and ethical context
- Explain the clinical and economic impact of drug shortages

Learning Objectives (Pharmacy Technicians)

- Summarize processes to secure the drug-supply chain, prevent harm from counterfeit drugs, and to understand and adhere to the new "Track and Trace" provisions of the Drug Supply Chain Security Act
- Explain the impact of the Act as it relates to the pharmacy's relationship with vendors, patients, and third party insurances
- Apply good practices to prevent legal issues in the purchase of medications

Key Factors that Led to the Drug Supply Chain Security Act:

The Drug Shortage Epidemic, Generic Price Increases, the Gray Market

Ernest Mario School of Pharmacy

Definition

- Drug Shortage is defined as a "period of time when the ***total supply*** of such drug available at the user level will not meet the demand for such drug at the user level. " H.R. 2245.

Drug Shortages: Scope of the Problem

- The number of drugs in limited supply was increasing but in light of action by the government, there has been a turn around
  - 2006: 70 shortages
  - 2010: 211 shortages
  - 2011: 267 shortages
  - 2014: 185 shortages
- Includes several critical medications
  - Medications used to treat cancer, pain and infections

Ventola, C. Lee. "The Drug Shortage Crisis in the United States." *Pharmacy and Therapeutics* 36.11 (2011): 740+. *PubMed*. Web. 2 Apr. 2012. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278171/?tool=pubmed>.

Cherici C, Frazier J, Feldman M, Gordon B, Petrykiw C, Russel W, et al. Premiere Inc. 2011 Mar. Navigating Drug Shortages in American Healthcare: A Premier Healthcare Alliance Analysis URL: http://www.premierinc.com/about/news/11-mar/drug-shortage-white-paper-3-28-11.pdf 2 Apr. 2012.

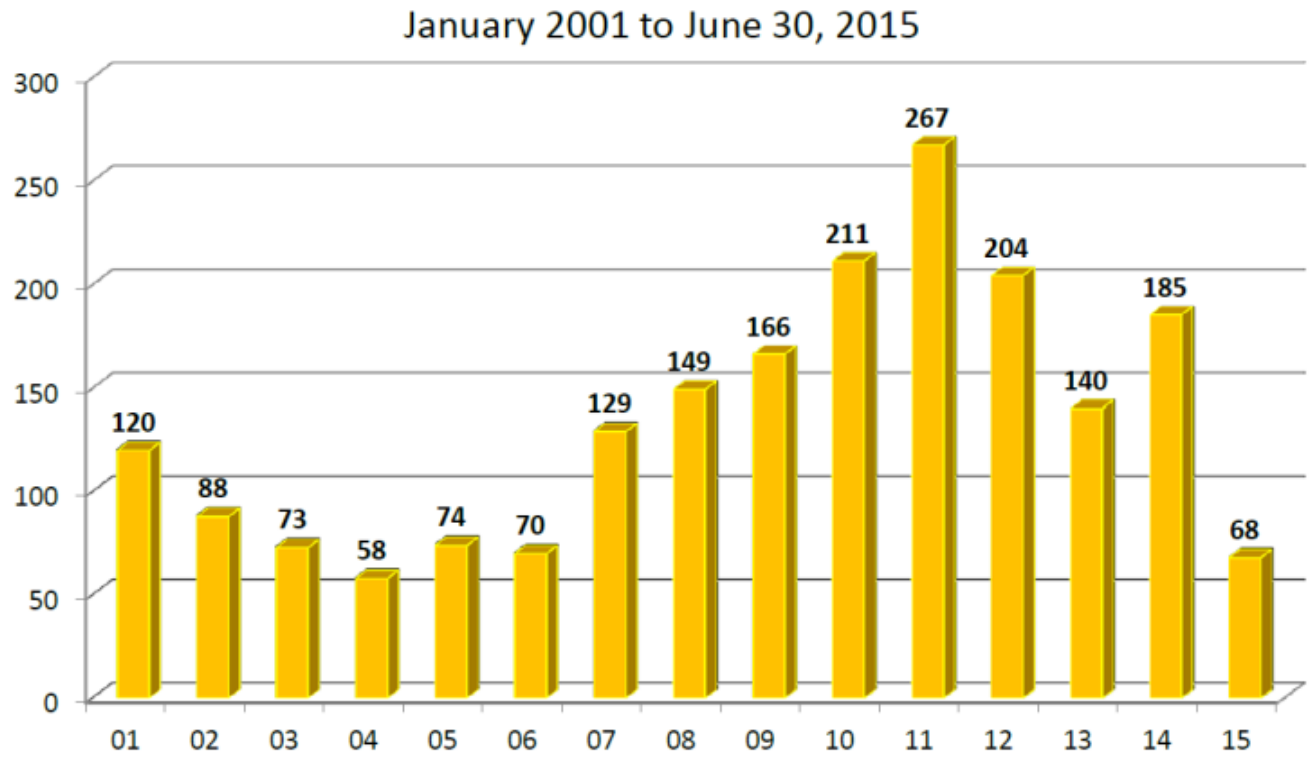
Medications Vulnerable to Drug Shortages

- Oncology Medications
- Injectable Medications
  - Morphine, electrolytes, propofol, etc…
- Generic Medications
- Single source/ concentrated market share Medications
- Grandfathered Medications
  - FDA's Unapproved Drugs Initiative

Ventola, C. Lee. "The Drug Shortage Crisis in the United States." *Pharmacy and Therapeutics* 36.11 (2011): 740+. *PubMed*. Web. 2 Apr. 2012. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278171/?tool=pubmed>.

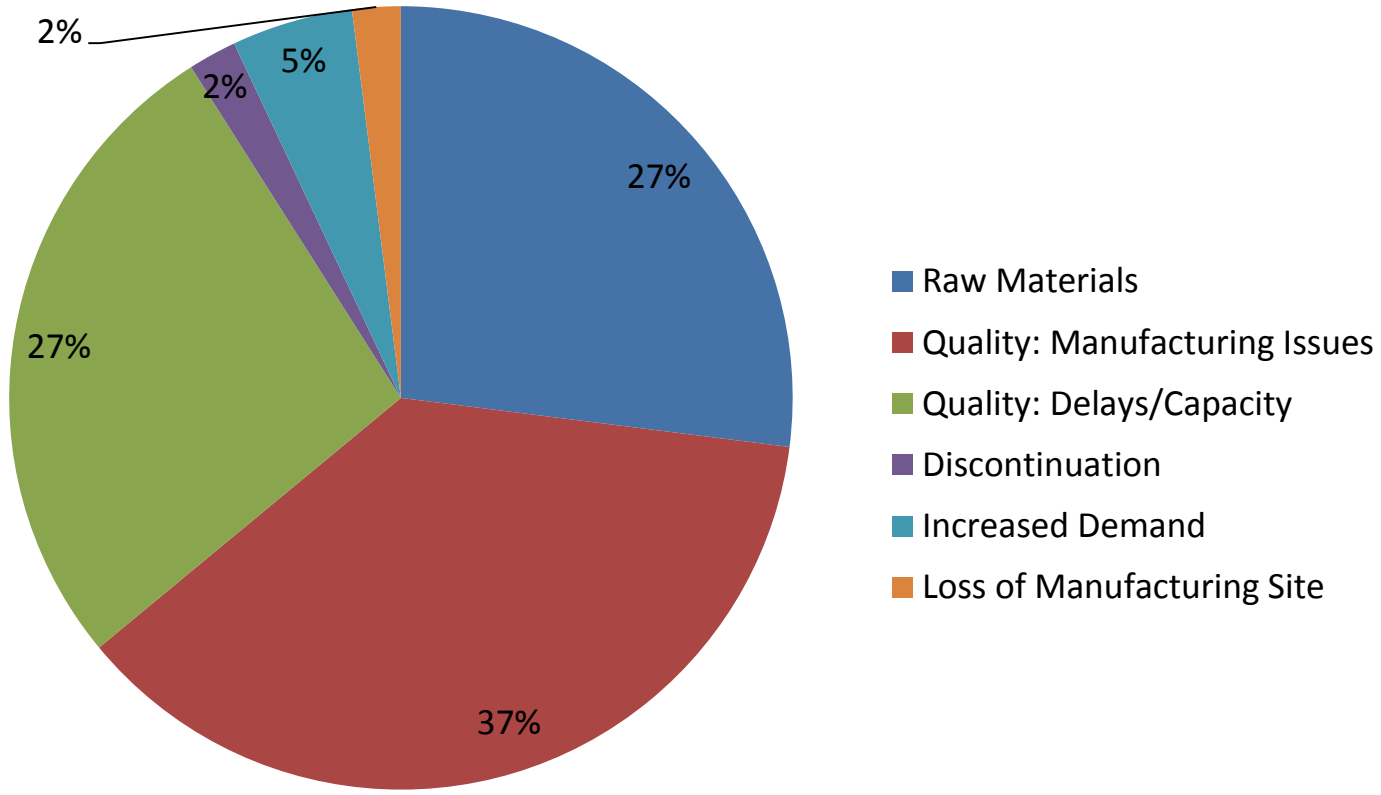
Drug Shortages: Scope of the Problem

- Historical trend in shortages



Fox, Erin. "National Drug Shortages." ASHP (2015): Web. 26 Aug 2015 <http://www.ashp.org/DocLibrary/Policy/DrugShortages/Drug-Shortages-Statistics.pdf>

Drug Shortages: Scope of the Problem



Adapted from 2015 FDA Drug Shortages Infographic

Drug Shortages: Potential Causes

- Quality/Manufacturing Issues
  - Natural disasters
  - Failure to meet GMP Standards
  - Delays in supply of raw materials
  - Recalls of defective lots
  - Company mergers
  - Discontinuation of unprofitable generics

Ventola, C. Lee. "The Drug Shortage Crisis in the United States." *Pharmacy and Therapeutics* 36.11 (2011): 740+. *PubMed*. Web. 2 Apr. 2012. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278171/?tool=pubmed>.
"Frequently Asked Questions About Drug Shortages." *FDA*. U.S. Department of Heath and Human Services, 14 Oct. 2011. Web. 2 Apr. 2012. <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050796.htm>.

Drug Shortages: Potential Causes

- **FDA can't require a firm to keep making a drug it wants to discontinue**
- Older drugs are discontinued by companies in favor of newer, more profitable drugs
  - Example: fewer firms are making older sterile injectable drugs

Drug Shortages: Potential Causes

- Industry Consolidation
  - Seven (7) manufacturers make up the large percentage of this market
- There are fewer manufacturers of certain multisource drugs
  - Therefore when one manufacturer stops making a drug, there is a larger impact

Drug Shortages: Potential Causes

- Generally, shortages are reported on a voluntary basis
  - If sole manufacturer of a medically necessary drug, must give 6 months' notice – See 21 U.S.C. 356c
- 38 shortages could have been prevented in 2010 had sufficient notice been given
- In 2011, 2012, and 2013 the FDA was able to prevent 195, 282, and 170, respectively, largely due to earlier reporting by manufacturers

Ventola, C. Lee. "The Drug Shortage Crisis in the United States." *Pharmacy and Therapeutics* 36.11 (2011): 740+. *PubMed*. Web. 2 Apr. 2012. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278171/?tool=pubmed>.

"Frequently Asked Questions About Drug Shortages." *FDA*. U.S. Department of Heath and Human Services, 14 Oct. 2011. Web. 2 Apr. 2012. <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050796.htm>.

Impact of Drug Shortages

- A study by the Premier Healthcare Alliance in March 2011 suggested the cost of purchasing alternative therapeutic products to those in shortage to be $200 million
- A survey conducted by ASHP and the University of Michigan indicated that hospital pharmacists are spending eight to twelve additional hours per week dealing with shortage
  - Annual labor costs of $216 million

Cherici C, Frazier J, Feldman M, Gordon B, Petrykiw C, Russel W, et al. Premiere Inc. 2011 Mar. Navigating Drug Shortages in American Healthcare: A Premier Healthcare Alliance Analysis URL: http://www.premierinc.com/about/news/11-mar/drug-shortage-white-paper-3-28-11.pdf 2 Apr. 2012.

"Frequently Asked Questions About Drug Shortages." *FDA*. U.S. Department of Heath and Human Services, 14 Oct. 2011. Web. 2 Apr. 2012. <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050796.htm>.

Impact of Drug Shortages

- Without access to the preferred drug treatment, clinicians must use alternatives, which may be less effective or associated with increased risk of adverse outcomes
  - 2011 ISMP Study: 1800 respondents reported over 1000 adverse drug events caused by shortages (25% were medication errors; 20% were adverse drug reactions)
  - 2011 American Hospital Association Survey: 82% of hospitals reported delayed treatment and more than half said they could not provide some patients with the recommended therapy

Impact of Drug Shortages

- In a 2013 study surveying 542 pharmacy directors of health care institutions in the U.S. various negative effects on patient outcomes were reported
- 50 directors gave data on estimated costs due to drug shortages and 73% estimated quarterly costs to be greater than $100,000

TABLE 3 Patient Outcomes Caused by Drug Shortages

Patient Outcome	Reports (N = 542 Individual Reports, 171 Respondents) (n, %)	
Alternative medication used	146	(85.3)
Delay of therapy	121	(70.8)
Increased patient monitoring necessary	84	(49.1)
Suboptimal treatment	83	(48.5)
Increased length of hospitalization	56	(32.7)
Treatment failure	27	(15.8)
Patient transferred to an institution with a supply of the needed medication	21	(12.3)
Re-admission caused by treatment failure	15	(8.8)
Death	2	(1.2)

McLaughlin M, Kotis D, Thomson K, et al. Effects on patient care caused by drug shortages. *JMCP.* 2013 19(9):783-8.

Impact of Drug Shortages

- Sub-optimal patient therapy
  - ↑ MD calls for substitutions
    - Leading to increased 3rd party calls/prior authorizations
  - ↓ Patient onset of treatment
  - ↓ Customer satisfaction
- Independents/Buying groups disadvantaged
  - Chain/corporate warehouses/contracts

1. Hunter, Graeme. "NERA Economic Consulting." *NERA: Publication*. NERA Economic Consulting, 19 Jan. 2011. Web. 02 Apr. 2012. <http://www.nera.com/67_7161.htm>.

Government Response to Drug Shortage Crisis

- President Obama signed Executive Order 13588 (Reducing Prescription Drug Shortages) in October 2011
  - Mandatory notification
  - Emphasis on price gouging
    - FDA will work with the Department of Justice (DOJ) to examine whether any secondary drug wholesalers or other market participants have responded to potential drug shortages by illegally hoarding medications or raising prices to gouge consumers
    - Based on its determination, DOJ, in coordination with other State and Federal regulatory agencies as appropriate, will undertake whatever enforcement actions, if any, it deems appropriate
  - Increased staffing at FDA
    - FDA will take steps to expand its current efforts to expedite its regulatory reviews, including reviews of new drug suppliers, manufacturing sites, and manufacturing changes

Executive Order 13588

- Modifications to Notification Requirements
  - Federal law requires drug manufacturers to notify FDA when production of critical drugs provided by only one manufacturer is being discontinued. *21 U.S.C. 356c*
    - Drug must be deemed medically necessary by FDA
    - FDA has no enforcement mechanism to penalize a drug maker for failing to report these problems
  - Executive order directs FDA to broaden reporting of potential shortages of certain prescription drugs

FDA Action

- Work with companies to address quality/ production issues
- Encourage remaining companies to ramp up production
- Expedite issues related to addressing shortages (e.g. new manufacturers, increased expiry, increased capacity, new raw material source, changes in specifications)
- Drug Shortage Program (DSP) began in 1999
  - Collaborating with FDA experts, industry, and external stakeholders
  - Communicate information to public

FDA Action

- In 2014, 101 shortages were prevented by FDA through various methods
  - Regulatory discretion (risk of quality/manufacturing issue able to be mitigated and was outweighed by benefit of the drug)
  - Expedited review (new manufacturing sites, suppliers, changes in specification or other changes)
  - Encouraging other firms to ramp up
  - Communication with DEA regarding firm's report to FDA regarding need for quota increase

FDA PowerPoint Presentation: *U.S. Drug Shortages,* 2011

FDA Action

- Early notification from manufacturers about possible shortages, as requested in the President's Executive Order 13588 of Oct. 31, 2011 and then codified into law in FDASIA, has enabled the FDA to work with manufacturers to restore production of many lifesaving therapies
  - Since the Executive Order, there has been a 6-fold increase in notifications to the FDA
- The FDA helped prevent 195 drug shortages in 2011 and 282 drug shortages in 2012, leading to a reduced number of new shortages in 2012

FDA PowerPoint Presentation: *U.S. Drug Shortages,* 2011

Congress Probes Generic Drug Price Increases

- Senators Bernie Sanders and Elijah Cummings in November 2014 announced they were investigating why some generic drug prices have risen hundreds to thousands of percent
- They claimed that between July 2013 and July 2014 prices of more than 1,200 generic medications increased and average of 448 percent
  - Albuterol sulfate's average cost for a bottle of 100 pills was $11 in in October 2013; by April 2014, it was $434
  - Doxycycline hyclate's average cost for a bottle of 500 tablets was $20 in October 2013; by April 2014 it was $1,849
  - Digoxin went from $0.12 a pill in July 2013 to $1.06 in June 2014
  - Divalproex sodium ER went from $0.27 a pill in July 2013 to $2.38 in June 2014
- They also cited a survey that found pharmacists ability to continue to serve patients was being substantially impaired by these price increases

Generic Drug Price Increases

- Out of a research sample of 4421 drug groups, 222 drug groups increased in price by 100% or more between Nov'13 and Nov'14
  - Some extreme cases (17 drug groups) where price increases of more than 1000% were seen
  - Tetracycline: between Nov'13 and Nov'14, it's per tablet price increased from $0.0345 to $2.3632
  - The rights to pyrimethamine (Daraprim) were purchased in August 2015 by a new company, Turing Pharmaceuticals, which promptly increased the price from $13.50 per tablet to $750 per tablet -- a 5,000 percent jump

http://www.forbes.com/sites/greatspeculations/2015/02/27/why-are-generic-drug-prices-shooting-up/#1fbdd443377e

Table 2. Cost Increases in Generic Drugs
July 2013 to December 2014

NDC Description	NADAC Per Unit Cost July 2013	NADAC Per Unit Cost December 2014	Price Change (%)
Amitriptyline Hydrochloride 100 mg tablet	$0.04	$1.08	2,487%
Amitriptyline Hydrochloride 150 mg tablet	$0.02	$0.13	691%
Captopril 12.5 mg tablet	$0.02	$0.90	5,316%
Captopril 100 mg tablet	$0.06	$1.88	3,281%
Clomipramine Hydrochloride 75 mg capsule	$0.42	$7.80	1,737%
Clomipramine Hydrochloride 50 mg capsule	$9.03	$8.29	-8%
Doxazosin Mesylate 1 mg tablet	$0.05	$0.56	1,051%
Doxazosin Mesylate 8 mg tablet	$0.11	$0.59	427%
Enalapril Maleate 20 mg tablet	$0.03	$0.43	1,461%
Enalapril Maleate 10 mg tablet	$0.02	$0.22	858%
Fluconazole 100 mg tablet	$0.14	$1.44	954%
Fluconazole 150 mg tablet	$2.39	$2.21	-8%
Mirtazapine 7.5 mg tablet	$0.13	$1.15	765%
Mirtazapine 45 mg tablet	$0.25	$0.32	30%
Pravastatin Sodium 10 mg tablet	$0.06	$0.38	502%
Pravastatin Sodium 80 mg tablet	$0.22	$0.58	162%
Prednisone 5 mg tablet	$0.02	$0.13	477%
Prednisone 50 mg tablet	$0.19	$0.27	40%
Tetracycline 500 mg capsule	$0.05	$8.53	17,582%
Tetracycline 250 mg capsule	$0.06	$4.06	6,991%
Ursodiol 300 mg tablet	$0.29	$4.48	1,408%
Ursodiol 500 mg tablet	$2.69	$2.69	0%

Congress Probes Generic Drug Price Increases

- In November 2014 legislation was introduced to require drug companies to reimburse Medicaid if they raise the prices of their generic drugs more quickly than the price of inflation
- Current law already requires these rebates when brand name prices increase
- The Medicaid Generic Drug Price Fairness Act, S. 2948 and H.R. 5748 would amend the law to apply this rebate provision to generic drugs
- The Congressional Budget Office estimated Medicaid could save over $500 million dollars over the next ten years

The Gray Market

- Market Factors including Drug Shortages and Drug Price Increases have led to the emergence of gray markets
  - Secondary and tertiary wholesalers
  - Diverted products
  - Sale of Products from overseas

- Creates ethical and logistical burdens
  - Choice of utilizing a lifesaving medication
  - Establishing proper pedigree
  - Choosing reliable wholesalers

Examples of the Gray Market

- Three California men and a Minnesota company were charged in an indictment in May 2015 in the Southern District of Ohio for their roles in a massive prescription drug diversion scheme
- The indictment alleges that Minnesota Independent Cooperative Inc. (MIC) engaged in a conspiracy to sell prescription drugs from illegal, unlicensed sources to wholesalers and pharmacies throughout the United States
- The 12-count indictment charges the defendants with conspiracy to commit mail and wire fraud, multiple counts of mail fraud, and conspiracy to distribute prescription drugs without a license and to make false statements

Examples of the Gray Market

- The United States Attorney for the Southern District of New York announced in December 2015 the unsealing of an indictment charging RANDY CROWELL, a/k/a "Roger," with fraudulently distributing, through his Utah-based wholesale distribution company, more than $100 million worth of prescription drugs obtained through a nationwide black market – drugs that were then dispensed by pharmacies to unsuspecting customers
  - To maximize their profits, Defendants allegedly focused on some of the most expensive medications on the market, including those used to treat HIV/AIDS
  - As detailed in the indictment, many of the bottles were purchased through the underground market and then distributed as safe, legitimate medications
  - To conceal the fact that they had been previously dispensed, the bottles were typically "cleaned" with hazardous chemicals such as lighter fluid before being transported and stored in conditions that were frequently unsanitary and insufficient to ensure the safety and efficacy of the medication

Examples of the Gray Market

- Abbott Laboratories has filed a federal lawsuit against distributors and pharmacies accusing them of importing and selling products from other countries and selling them illegally in the US
  - The company says the diversion activity affects its FreeStyle brand of glucose testing strips used by diabetics and is costing it millions of dollars every year
  - The strips can be purchased at a lower price overseas, with the difference allowing the defendants to make a "hefty profit" from their sale in the US
  - Wholesalers are alleged to be at the center of the conspiracy, according to the plaintiff

Case Study

- As the senior pharmacy technician at Smith's Pharmacy, one of your responsibilities is the ordering on non-CDS medications and supplies
- The pharmacy needs to re-order diabetic test strips
- What are some things you should look for?

Case Study Cont.

- Is the wholesaler licensed?
- Price comparisons?
- Are there any special indicators relating to the product?
- History of purchases?
- Billing issues?

The Emergence of a Gray Market

- U.S. Representative Elijah Cummings is investigating the "gray market" sales of drugs in short supply
- As part of this investigation, Cummings obtained confidential information relating to companies that allegedly charge prices many times higher than those negotiated with authorized manufacturers and distributers
- The investigation has included wholesalers, pharmacies, and other healthcare providers

http://democrats.oversight.house.gov/index.php?option=com_content&view=article&id=5445&Itemid=107

The Emergence of a Gray Market

- Drugs reviewed by Congressman Cummings include:
  - *Cytarabine*
  - *Paclitaxel*
  - *Leucovorin*
  - *Fluorouracil*
  - *Magnesium sulfate*
- Specially licensed brokers who seek out supplies of medication in short supply, secure the remaining supplies and remarket them with significant markups
  - Price increases: 200% to 4500%
  - Average Increase: 650%
  - Cytarabine normal price: $12/vial Increased to $990/vial

http://democrats.oversight.house.gov/index.php?option=com_content&view=article&id=5445&Itemid=107
Institute for Safe Medication Practices. 2011 Aug 25. Gray Market, Black Heart: Pharmaceutical Gray Market Finds a Disturbing Niche During the Drug Shortage Crisis URL: http://www.ismp.org/Newsletters/acutecare/showarticle.asp?ID=3 02 Apr. 2012.

Drug Pedigree

- Gray Market medications can exchange hands many times
- Only about ½ the states have drug pedigree laws (number is growing)
  - Enforced at the state level so every law is different
- Creates uncertainty about authenticity, the proper storage and handling, and the viability of the drug

1. Institute for Safe Medication Practices. 2011 Aug 25. Gray Market, Black Heart: Pharmaceutical Gray Market Finds a Disturbing Niche During the Drug Shortage Crisis URL: http://www.ismp.org/Newsletters/acutecare/showarticle.asp?ID=3 02 Apr. 2012.

Good Practices

- Recognize that the drugs may be counterfeit, stolen, diverted, mishandled, and/or adulterated
- Develop an institutional policy on how to deal with gray vendors
- Purchase only from authorized distributors or a verified-accredited wholesale distributor
- Be wary of deep discounts

1. Institute for Safe Medication Practices. 2011 Aug 25. Gray Market, Black Heart: Pharmaceutical Gray Market Finds a Disturbing Niche During the Drug Shortage Crisis URL: http://www.ismp.org/Newsletters/acutecare/showarticle.asp?ID=3 02 Apr. 2012.
2. "FDA Issues Notification Regarding Risks of Purchasing Unapproved Injectable Cancer Medications from Unlicensed Sources." - *National Association of Boards of PharmacyÂ® (NABPÂ®)*. Web. 02 Apr. 2012. <http://www.nabp.net/news/fda-issues-notification-regarding-risks-of-purchasing-unapproved-injectable-cancer-medications-from-/>

Good Practices

- Require non-authorized distributors to provide pedigree
- Keep a list of suspect distributors
- Compare with original manufacturer's product to see if there are differences
- Report suspect medications and pedigree violations to the BOP, FDA, and FTC

1. Institute for Safe Medication Practices. 2011 Aug 25. Gray Market, Black Heart: Pharmaceutical Gray Market Finds a Disturbing Niche During the Drug Shortage Crisis URL: http://www.ismp.org/Newsletters/acutecare/showarticle.asp?ID=3 02 Apr. 2012.

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Combating the Gray Market:

The Drug Supply Chain Security Act

Ernest Mario School of
Pharmacy

Important Update from FDA

- [Updated 10/28/2015] FDA issued guidance to inform industry that it does not intend to take action against dispensers who, **prior to March 1, 2016**, accept ownership of product without receiving the product tracing information, as required by section 582(d)(1)(A)(i) of the FD&C Act
- Prior to March 1, 2016, FDA also does not intend to take action against dispensers who do not capture and maintain the product tracing information, as required by section 582(d)(1)(A)(iii) of the FD&C Act
- This compliance policy does not extend to transactions in which dispensers must provide the subsequent owner with product tracing information. Additionally, other product tracing requirements regarding authorized trading partners and verification related to suspect and illegitimate product (including quarantine, investigation, notification and recordkeeping) still apply and are in effect for dispensers.

Legislative History

- The Drug Quality and Security Act (DQSA), was signed into law by President Obama on November 27, 2013
- Title II of the Act is the Drug Supply Chain Security Act
- Outlines critical steps to build an electronic, interoperable system to ***identify and trace*** certain prescription drugs as they are distributed in the United States

Goals

- Establish standardized documentation to be used by members of the pharmaceutical distribution supply chain to convey the ***transaction information***, ***transaction history***, and ***transaction statement*** to the subsequent purchaser of a product and to facilitate the exchange of lot level data
- Within ten years, the system will facilitate the exchange of information at the individual package level about where a drug has been in the supply chain
- The new system will:
  - Enable verification of the legitimacy of the drug product identifier down to the package level;
  - Enhance detection and notification of illegitimate products in the drug supply chain; and
  - Facilitate more efficient recalls of drug products.

Goals (cont.)

- **Product identification:** Manufacturers and repackagers to put a unique product identifier on certain prescription drug packages, for example, using a bar code that can be easily read
- **Product tracing:** Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) in the drug supply chain to provide information about a drug and who handled it each time it is sold in the U.S. market
- **Product verification**: Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) to establish systems and processes to be able to verify the product identifier on certain prescription drug packages
- **Detection and response**: Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) to quarantine and promptly investigate a drug that has been identified as *suspect*, meaning that it may be counterfeit, unapproved, or potentially dangerous

Goals (cont.)

- **Notification:** Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) to establish systems and processes to notify FDA and other stakeholders if an illegitimate drug is found
- **Wholesaler licensing:** Wholesale drug distributors to report their licensing status and contact information to FDA. This information will then be made available in a public database.
- **Third-party logistics provider licensing:** Third-party logistic providers, those who provide storage and logistical operations related to drug distribution, to obtain a state or federal license

Who Will the Act Effect?

- Drug manufacturers
- Wholesale drug distributors
- Repackagers
- Many dispensers (primarily pharmacies)

Key Terms

- **Dispenser**: 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 does not include a person who dispenses only products to be used in animals in accordance with section 512(a)(5).
- **Repackager**: a person who owns or operates an establishment that repacks and relabels a product or package for further sale; or distribution without a further transaction
- **Wholesale distributor**: a person (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale distribution

Key Terms (cont.)

- The term "**product**" means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution), but for purposes of section 582, does not include. . . blood or blood components intended a drug compounded in compliance with section 503A or 503B.

Key Terms (cont.)

- **What is a transaction?**
  - The term `transaction' means the transfer of product between persons in which a change of ownership occurs
- **There are <u>multiple exceptions</u>**
  - intracompany distribution of any product between members of an affiliate or within a manufacturer;
  - the distribution of a product among hospitals or other health care entities that are under common control;
  - the distribution of a product for emergency medical reasons;
  - the dispensing of a product pursuant to a prescription
  - the distribution of minimal quantities of product by a licensed retail pharmacy to a licensed practitioner for office use;
  - the distribution of a product pursuant to the sale or merger of a pharmacy or pharmacies or a wholesale distributor or wholesale distributors

Key Terms (cont.)

- **Transaction history**: a statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.
  - Pedigree
- **Transaction information:**
  - (A) the proprietary or established name or names of the product;
  - (B) the strength and dosage form of the product;
  - (C) the National Drug Code number of the product;
  - (D) the container size;
  - (E) the number of containers;
  - (F) the lot number of the product;
  - (G) the date of the transaction;
  - (H) the date of the shipment, if more than 24 hours after the date of the transaction;
  - (I) the business name and address of the person from whom ownership is being transferred; and
  - (J) the business name and address of the person to whom ownership is being transferred.

Key Terms (cont.)

- **Transaction statement**: a statement, in paper or electronic form, that the entity transferring ownership in a transaction—
  - (A) is authorized as required under the Drug Supply Chain Security Act;
  - (B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;
  - (C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;
  - (D) did not knowingly ship a suspect or illegitimate product;
  - (E) had systems and processes in place to comply with verification requirements under section 582;
  - (F) did not knowingly provide false transaction information; and
  - (G) did not knowingly alter the transaction history.

Key Terms (cont.)

- A wholesale distributor that purchases "direct" is buying from a manufacturer, a repackager that purchased direct or an exclusive distributor
- Under the DSCSA, when a wholesale distributor purchases "direct," they are not required to include lot number, previous transaction date or previous ship date in the transaction data that they pass to customers
- Instead, they should include a transaction statement, which shall state that such wholesale distributor, or a member of the affiliate of such wholesale distributor, purchased the product directly from the manufacturer, exclusive distributor of the manufacturer, or repackager that purchased the product directly from the manufacturer

Dispenser Requirements

- Beginning July 1, 2015 (now March 1, 2016), a dispenser—
  - shall not accept ownership of a product, unless the previous owner prior to, or at the time of, the transaction, provides transaction history, transaction information, and a transaction statement;
  - prior to, or at the time of, each transaction in which the dispenser transfers ownership of a product (but not including dispensing to a patient or returns) shall provide the subsequent owner with transaction history, transaction information, and a transaction statement for the product, except that the requirements of this clause shall not apply to sales by a dispenser to another dispenser to fulfill a specific patient need ("KOW")
  - shall capture transaction information (including lot level information, if provided), transaction history, and transaction statements, as necessary to investigate a suspect product, and maintain such information, history, and statements for not less than **6 years** after the transaction.

Dispenser Requirements (cont.)

- Agreements with third parties:
  - A dispenser may enter into a written agreement with a third party, including an authorized wholesale distributor, under which the third party confidentially maintains the transaction information, transaction history, and transaction statements on behalf of the dispenser
- If a dispenser enters into such an agreement, the dispenser shall maintain a copy of the written agreement ***and shall not be relieved of the obligations*** of the dispenser under this subsection

Dispenser Requirements (cont.)

- Returns
  - **Saleable returns**: A dispenser may return product to the trading partner from which the dispenser obtained the product without providing the information required.
  - **Nonsaleable returns**: A dispenser may return a nonsaleable product to the manufacturer or repackager, to the wholesale distributor from whom such product was purchased, to a returns processor, or to a person acting on behalf of such a person without providing the information required.

Dispenser Requirements (cont.)

- Recalls and Requests for Data
  - In the event of a recall or for the purpose of investigating a suspect or an illegitimate product, a dispenser shall, not later than 2 business days after receiving the request or in another such reasonable time as determined by the Secretary, based on the circumstances of the request, provide the applicable transaction information, transaction statement, and transaction history which the dispenser received from the previous owner, which shall not include the lot number of the product, the initial transaction date, or the initial shipment date from the manufacturer unless such information was included in the transaction information, transaction statement, and transaction history provided by the manufacturer or wholesale distributor to the dispenser.
  - The dispenser may respond to the request by providing the applicable information in either paper or electronic format.

Dispenser Requirements (cont.)

- Recalls and Requests for Data (cont.)
  - Until the date that is 4 years after the date of enactment of the Drug Supply Chain Security Act, the Secretary or other appropriate Federal or State official shall grant a dispenser additional time, as necessary, only with respect to a request to provide lot level information that was provided to the dispenser in paper format, limit the request time period to the 6 months preceding the request or other relevant date, and, in the event of a recall, the Secretary, or other appropriate Federal or State official may request information only if such recall involves a serious adverse health consequence or death to humans.

Dispenser Requirements (cont.)

- Authorized trading partners – Beginning not later than January 1, 2015, the trading partners of a dispenser may be only authorized trading partners
- Who is Authorized?
  - (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 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 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.

Dispenser Requirements (cont.)

- Beginning not later than January 1, 2015, a dispenser shall have systems in place to enable the dispenser to:
  - Respond upon making a determination that a product in the possession or control of the dispenser is a suspect product, or upon receiving a request for verification from the Secretary that has made a determination that a product within the possession or control of a dispenser is a suspect product

Dispenser Requirements (cont.)

- Suspect Products
  - quarantine such product within the possession or control of the dispenser from product intended for distribution until such product is cleared or dispositioned; and
  - promptly conduct an ***investigation*** in coordination with trading partners, as applicable, to determine whether the product is an illegitimate product.

Dispenser Requirements (cont.)

- Suspect Product Investigation shall include:
  - (I) beginning 7 years after the date of enactment of the Drug Supply Chain Security Act, verifying whether the lot number of a suspect product corresponds with the lot number for such product;
  - (II) beginning 7 years after the date of enactment of such Act, verifying that the product identifier, including the standardized numerical identifier, of at least 3 packages or 10 percent of such suspect product, whichever is greater, or all packages, if there are fewer than 3, corresponds with the product identifier for such product;
  - (III) validating any applicable transaction history and transaction information in the possession of the dispenser; and
  - (IV) otherwise investigating to determine whether the product is an illegitimate product.

Dispenser Requirements (cont.)

- Cleared product – If the dispenser makes the determination that a suspect product is not an illegitimate product, the dispenser shall promptly notify the Secretary, if applicable, of such determination and such product may be further distributed or dispensed.

Dispenser Requirements (cont.)

- Illegitimate product – Upon determining, in coordination with the manufacturer, that a product in the possession or control of a dispenser is an illegitimate product, the dispenser shall—
  - (I) disposition the illegitimate product within the possession or control of the dispenser;
  - (II) take reasonable and appropriate steps to assist a trading partner to disposition an illegitimate product not in the possession or control of the dispenser; and
  - (III) retain a sample of the product for further physical examination or laboratory analysis of the product by the manufacturer or Secretary (or other appropriate Federal or State official) upon request by the manufacturer or Secretary (or other appropriate Federal or State official), as necessary and appropriate.

Dispenser Requirements (cont.)

- A dispenser shall keep records of the investigation of a suspect product for not less than 6 years after the conclusion of the investigation
- A dispenser shall keep records of the disposition of an illegitimate product for not less than 6 years after the conclusion of the disposition

Dispenser Requirements (cont.)

- Making a notification – Upon determining that a product in the possession or control of the dispenser is an illegitimate product, the dispenser shall notify the Secretary and all immediate trading partners that the dispenser has reason to believe may have received such illegitimate product of such determination not later than **24 hours** after making such determination.

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The History and Implications of The Drug Supply Chain Security Act

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