

Drug Pricing in the Pharmaceutical Supply Chain



Overview of the Supply Chain NABP

***October 31, 2016
California Assembly Committee on Health
Sacramento, CA***

National Association of Boards of Pharmacy (NABP)

- NABP - nonprofit association founded in 1904
- Members – Include State and Territorial Boards of Pharmacy
- NABP is the independent, international, and impartial association that assists its member boards and jurisdictions for the purpose of protecting the public health.



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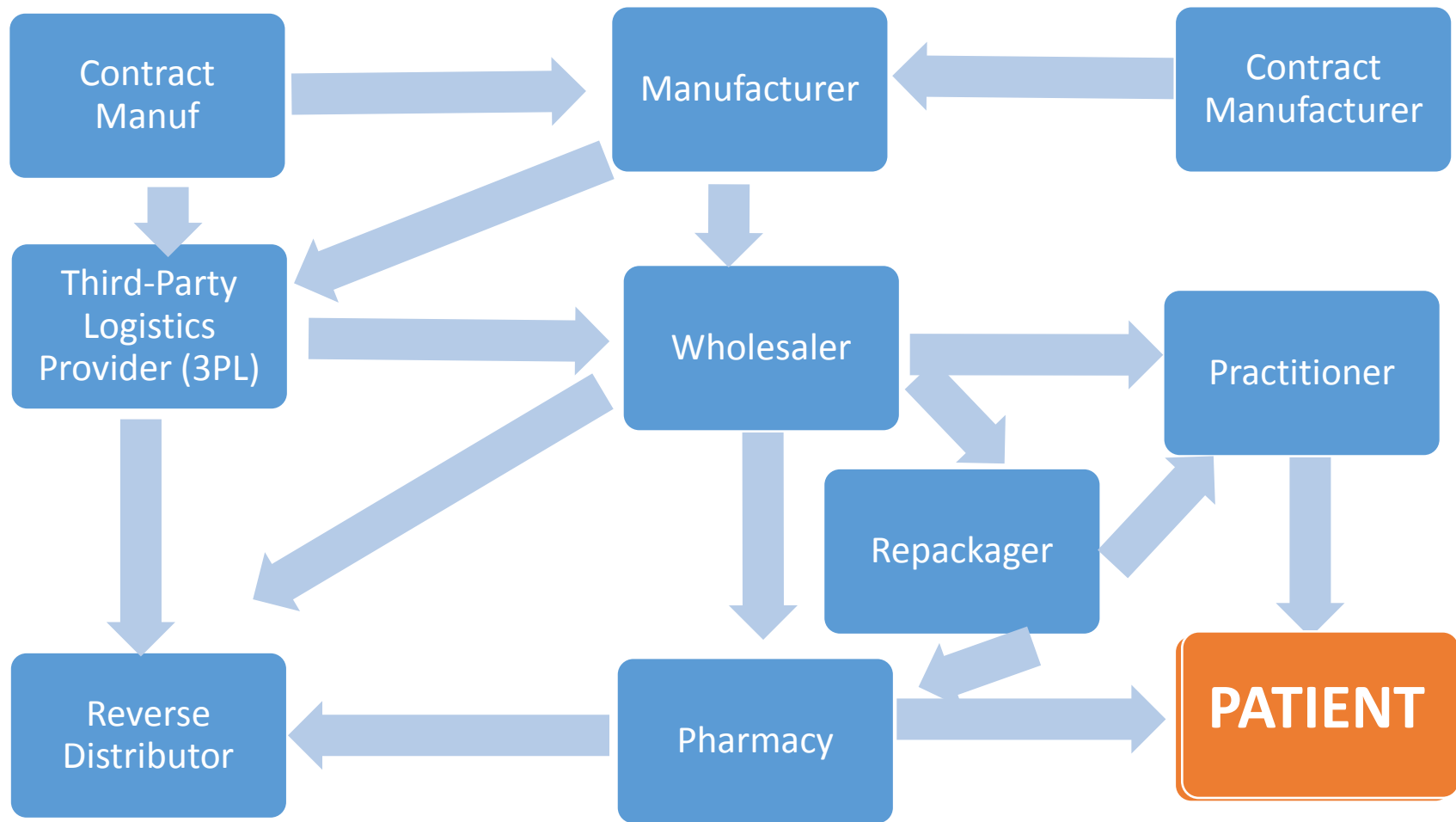
DSCSA

- Title II of Drug Quality and Security Act
- DSCSA - Drug Supply Chain Security Act
 - Enacted November 27, 2013
 - Changed the way Rx drugs are distributed
 - Great promise for verification of a drug products Serial Number
 - Is not a single remedy to keeping Supply Chain Safe
 - Many questions and issues to resolve

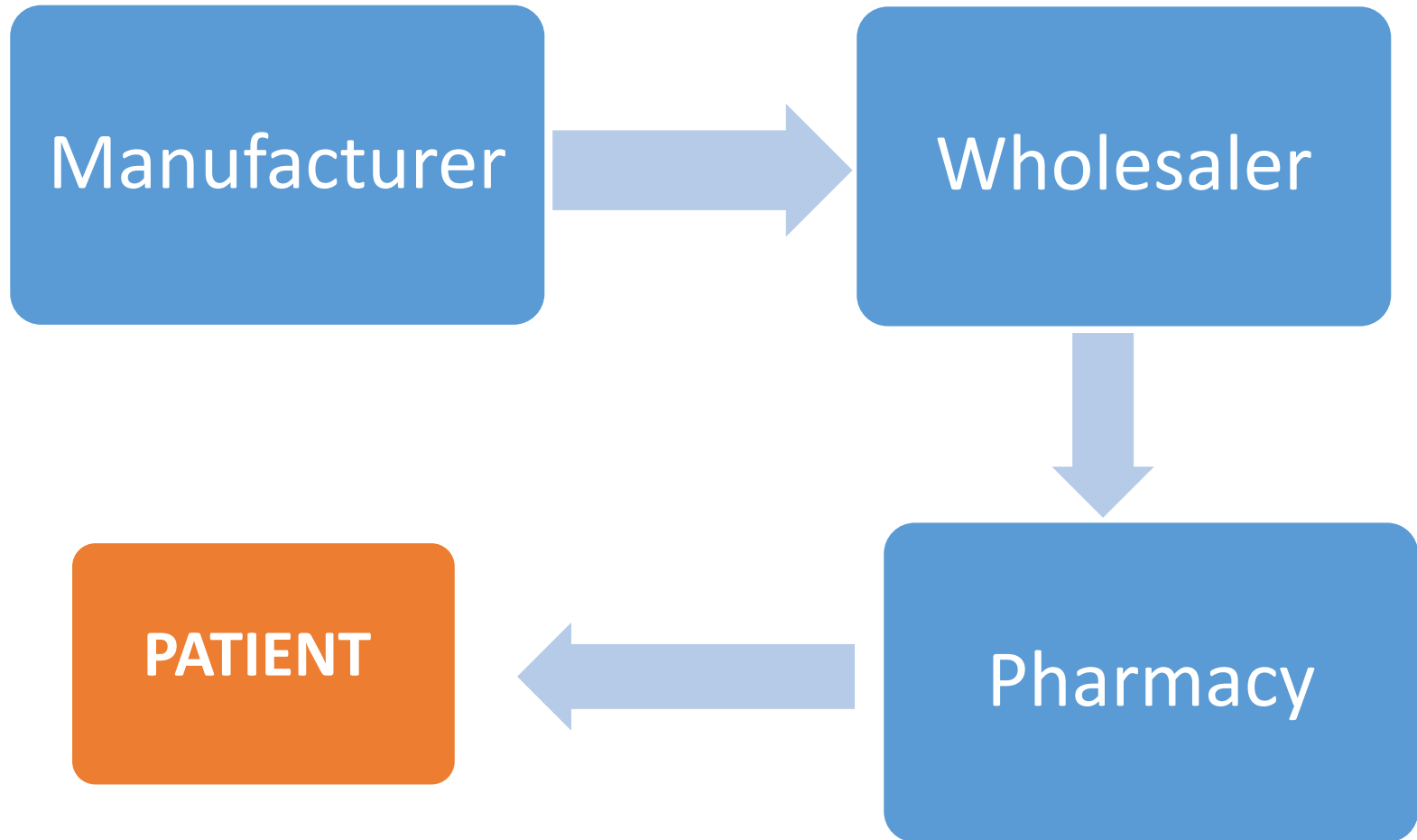


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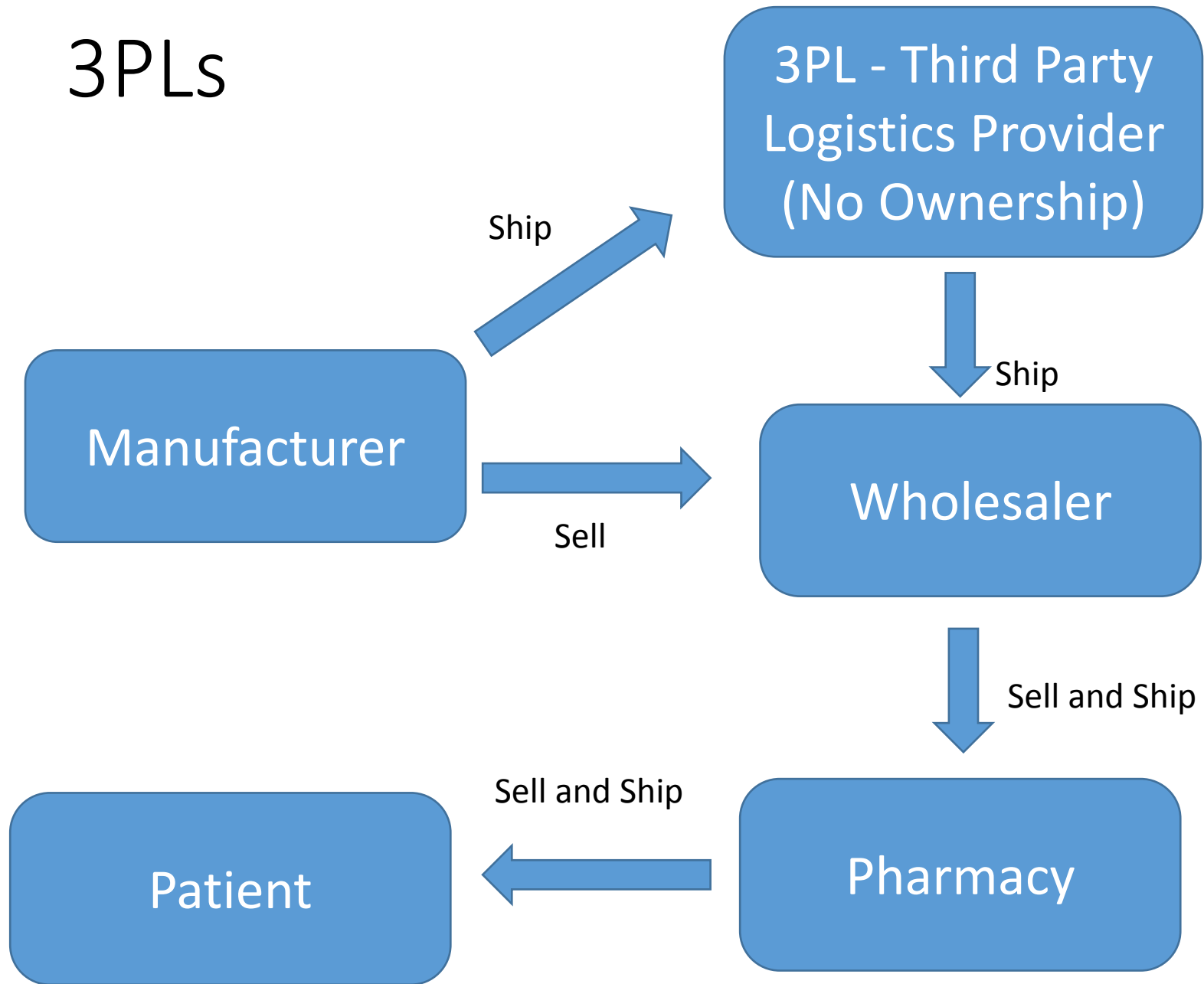
The Supply from Cradle to Grave



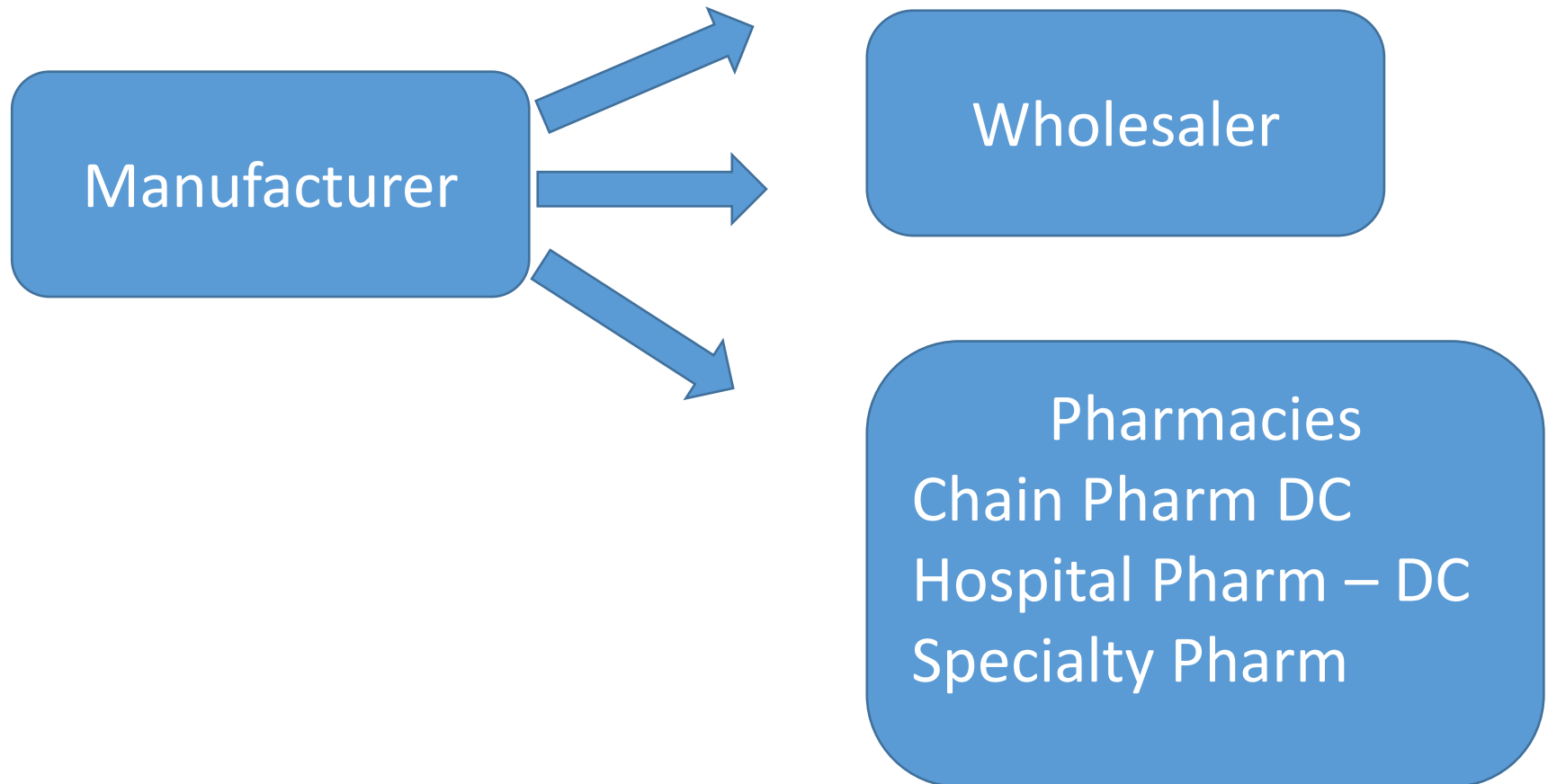
Simplified Distribution Model



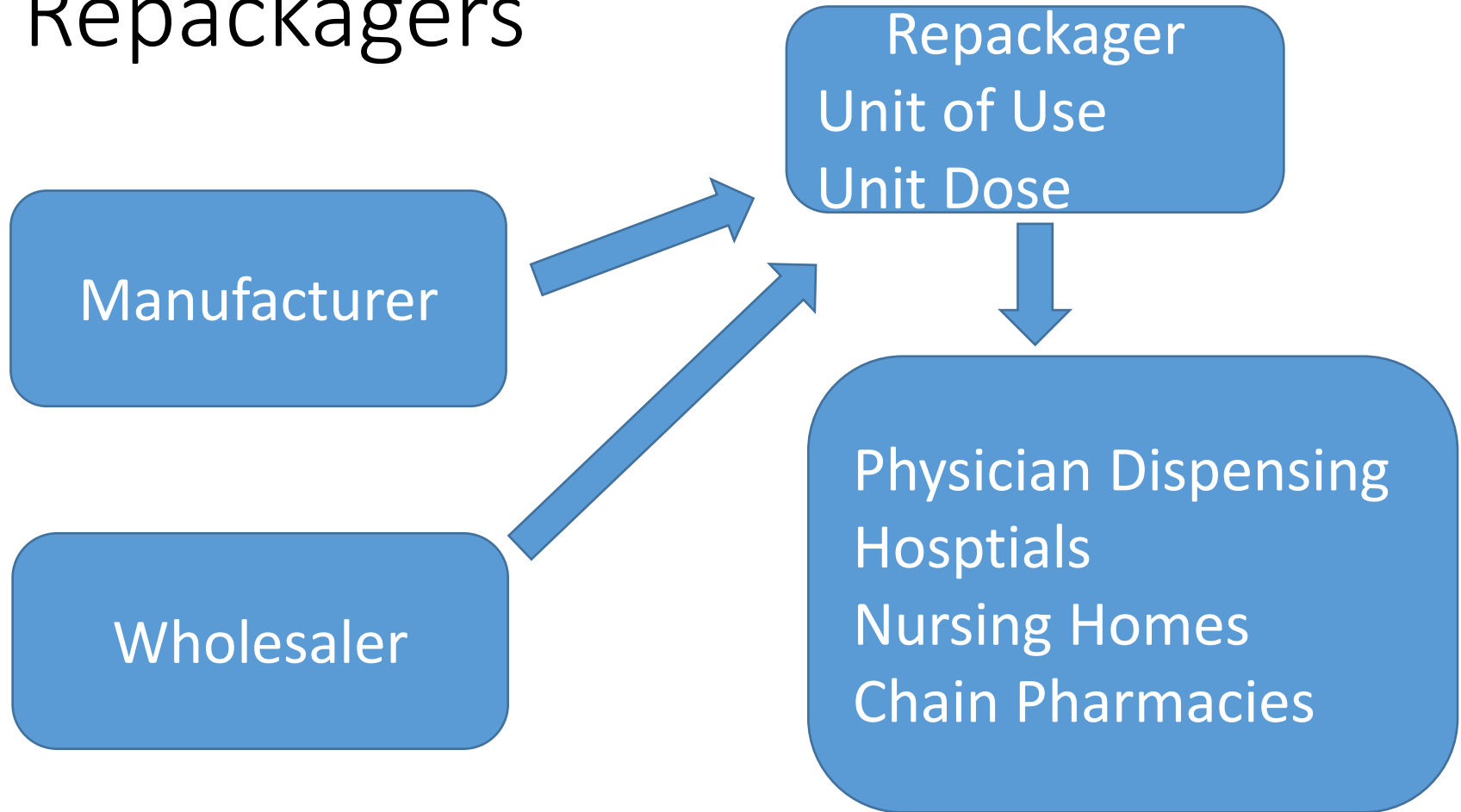
3PLs



Manufacturer Direct Distribution



Repackagers



Outsourcing Facilities 503B

Manufacturer
Finished
Approved

Wholesaler
Approved
Finished

API (Drug
Powder)
Distributor



Outsourcing Facility

- New Entity result of NECC
- Compounds – Sterile Drugs
- cGMPs
- Drugs not Approved
- Dist to Hospitals and Practitioners
- Can be large scale production

Manufacturer



Wholesaler

National Primary (Big 3)

National 2nd Tier

Regional

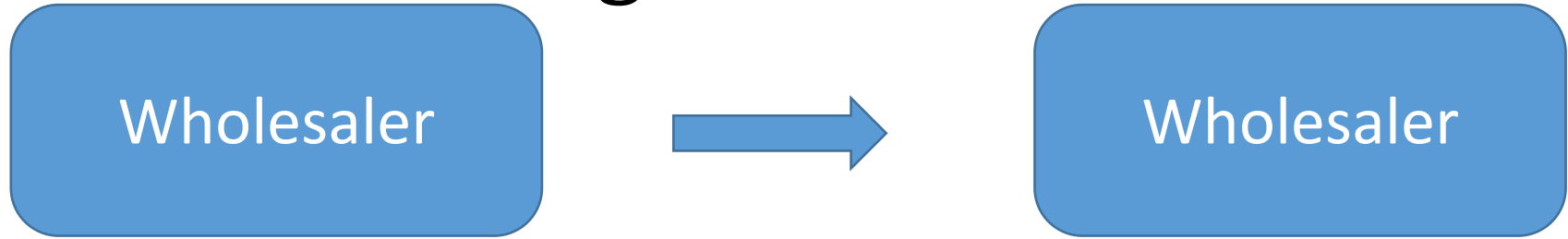
Single Site – Regional Dist

Specialty Markets

Specialty Products

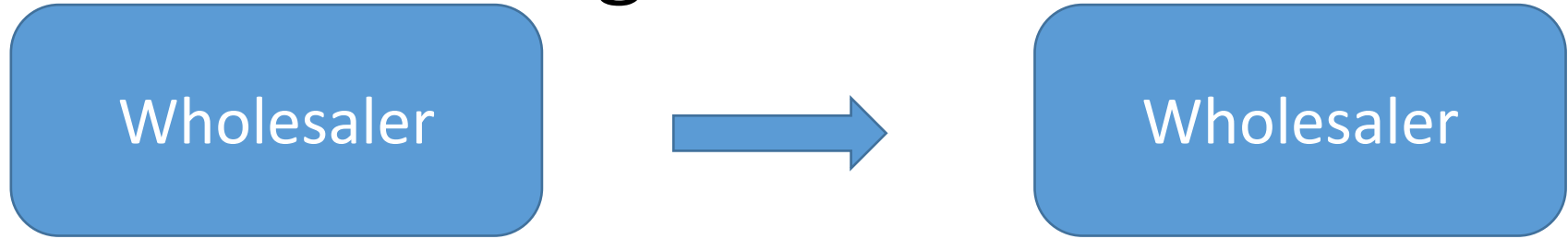
Drug
Wholesalers

Drug Wholesalers



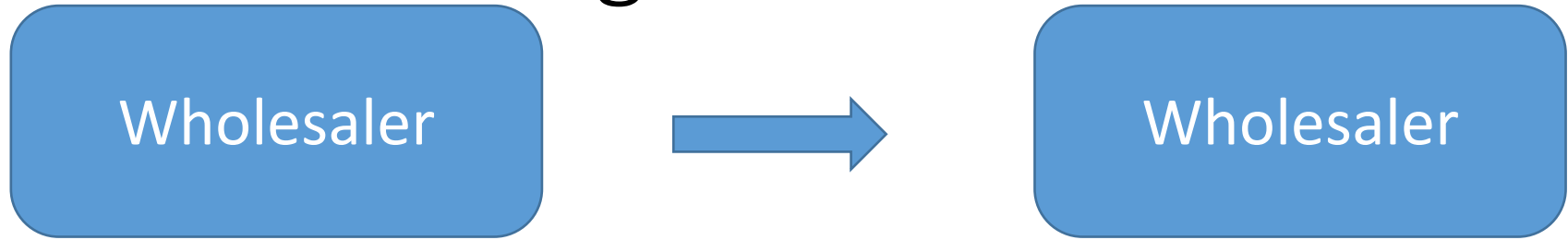
- Multiple movements between Wholesalers x7
- Falsified Transaction Histories
- Purchases from Wholesalers in Puerto Rico in violation of Manufacturer contracts
- Purchases from pharmacies purchasing under GPO pricing

Drug Wholesalers



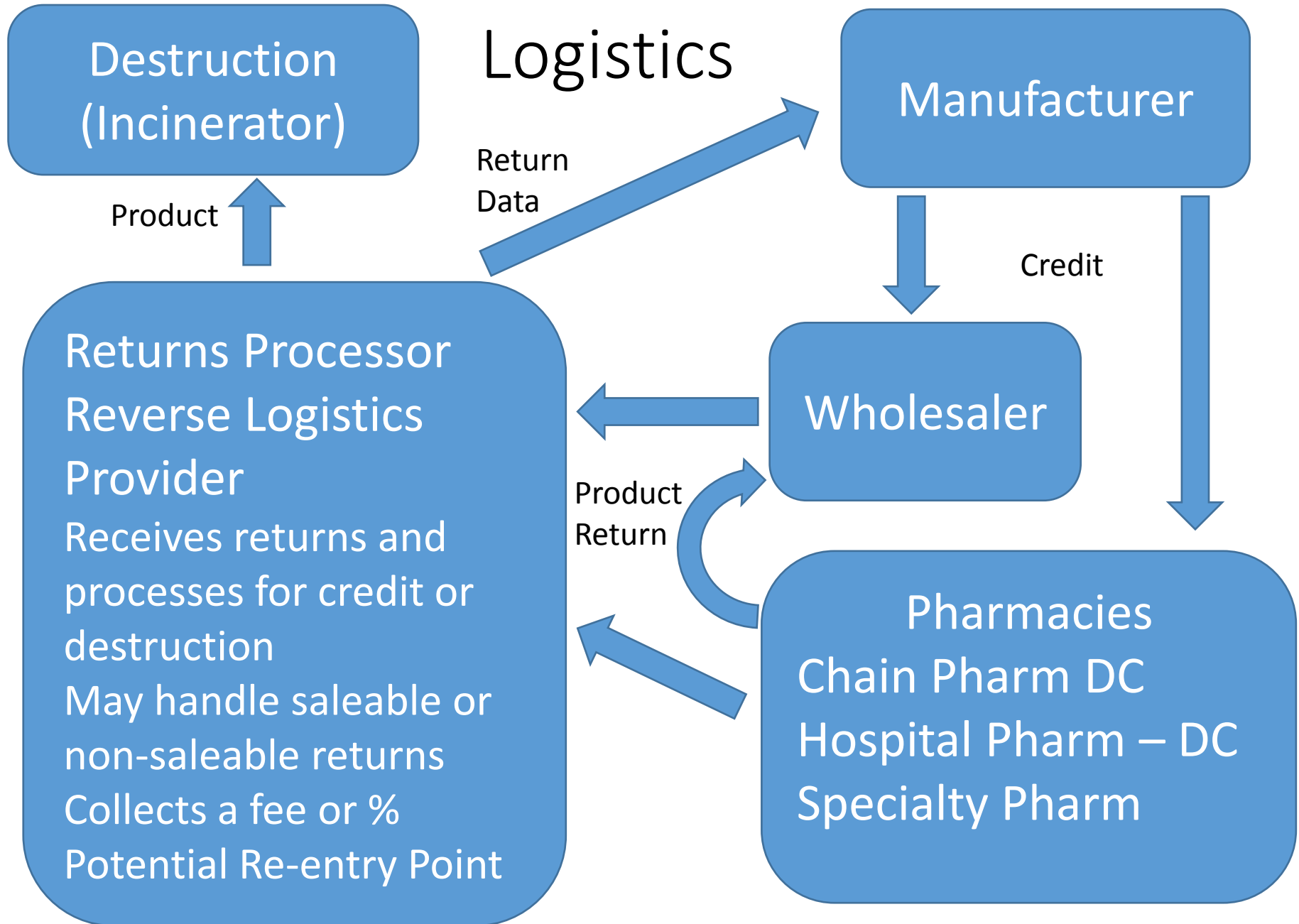
- Purchases from pharmacies - shortage drugs
- Purchases from Wholesalers that are co-located with pharmacies purchasing under LTC contracts
- Wholesalers selling drugs purchased by affiliated pharmacies

Drug Wholesalers



- Introduction point for counterfeit or substandard drugs
- Increased risk is directly proportional to the increased number of transactions, requiring greater due diligence by wholesalers
- Safest drug supply has the fewest movements from manufacturer to patient

Reverse Logistics



Understanding the Threat

May 2015- \$400 Million

May 7, 2015: Three California Men and Minnesota Corporation Indicted in Nationwide Prescription Drug Diversion Scheme

Throughout the course of the conspiracy charged in the indictment, using these fraudulent pedigree documents, Miller and MIC sold approximately \$393 million worth of prescription drugs to wholesalers and retail pharmacies throughout the United States, including to multiple customers in the Southern District of Ohio.

Source: May 7, 2015 DOJ press release



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April 29, 2016: Manhattan U.S. Attorney Announces Arrest Of Black Market Distributor Of Diverted HIV Medications Worth Approximately \$4 Million

From at least in or about September 2013 until April 2016, DELEONROSA was part of a black market distribution network that distributed bulk quantities of second-hand HIV prescription drugs to unsuspecting consumers. In particular, the members of the black market distribution ring would initially obtain the HIV prescription drugs by purchasing these drugs from patients to whom these medications were originally prescribed. The prescription HIV bottles were then collected and the labels (containing the patients' names) were removed using dangerous substances, including lighter fluid and other potentially hazardous chemicals. Through this process, the members of the black market distribution network made the bottles appear new in order to conceal the fact that the bottles had previously been dispensed to patients. This process allowed the bottles eventually to be re-sold to pharmacies and unsuspecting consumers. Consumers who eventually received these second-hand prescription HIV medications were not aware that the prescription bottles had been previously sold, treated with potentially hazardous chemicals, and possibly not stored under conditions sufficient to maintain their medical efficacy.



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What's Being Observed



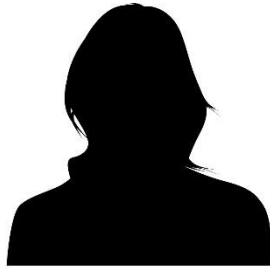
Expensive Rx Drugs are collected from patients and they are paid a small fee

Drugs with Pharmacy label are cleaned with Lighter fluid or goo gone and move back through wholesalers and pharmacies.

Sophisticated Diversion Schemes



Recipient List
Seller



Patient
Recruiter



Patient
Transporter



Physician - Rx
Source



Pharmacy
Owner



Medication
Cleaner

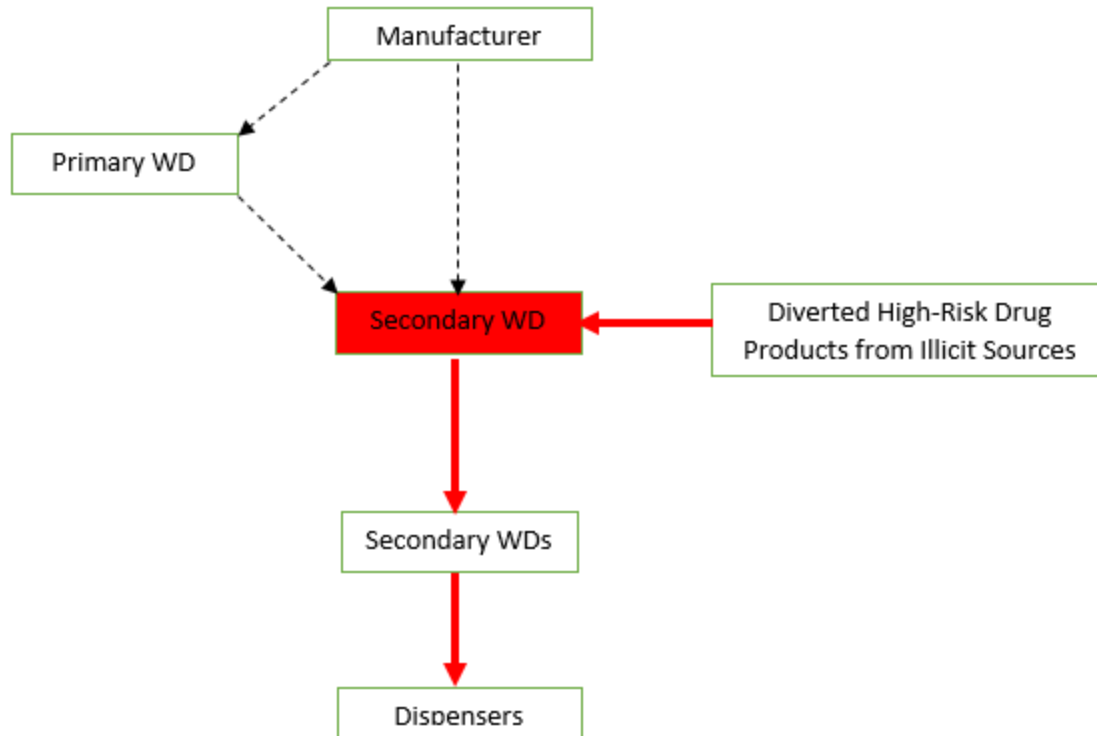


Pharmacy
Owner



Wholesale
Owner

**Transaction History
Validation Scenario 1**

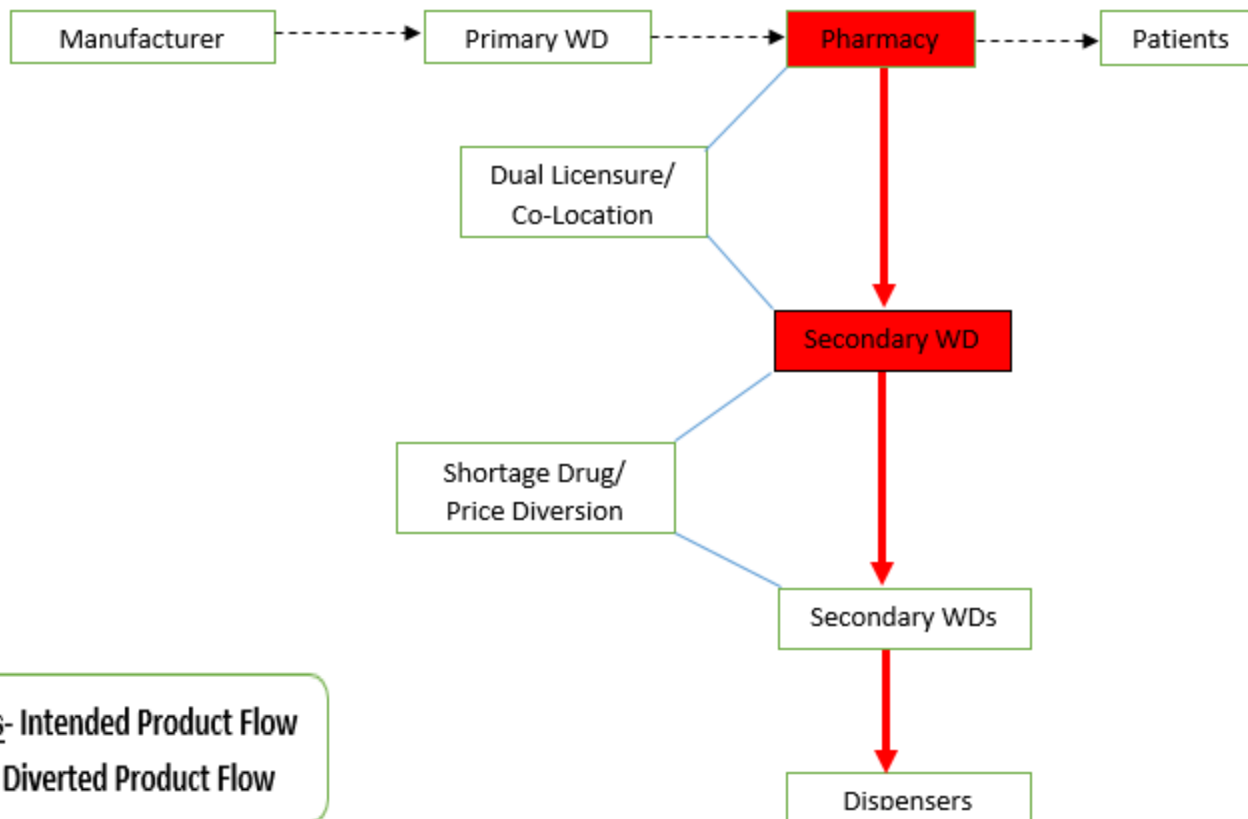


Black Lines- Purported Product Flow
Red Lines- Diverted Product Flow



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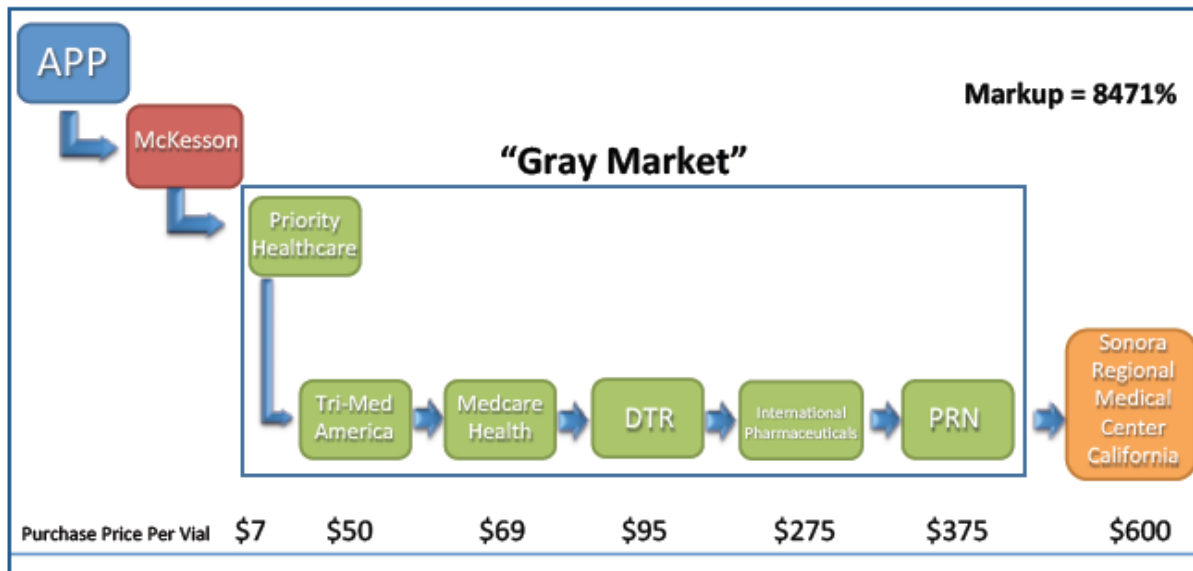
Transaction History Validation Scenario 2



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July 2012 Congressional Drug Shortages Report

In the drug chain illustrated below, which documents the shipment of 25 vials of a chemotherapy drug called fluorouracil in September 2011, the leakage point was a Maryland pharmacy called Priority Healthcare. Instead of dispensing the drug to patients, the owner of this company, Marianna Pesti, sold the vials to a New Jersey distributor called Tri-Med America, which was owned by Ms. Pesti's husband, Gabor Szilagyi. The drugs were sold five more times before reaching their end user, a hospital in California.



<http://democrats.oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/7.25.12%20Staff%20Report%20Shining%20Light%20on%20the%20Gray%20Market.pdf>



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Drug Distribution – Critical Safety and Effectiveness Points

- Storage, Handling, Shipment – Most drugs require storage between 68 – 77 F.
- Refrigeration critical for biologicals
- Freezing can deactivate vaccines
- Sources – Must be a strong emphasis on Legitimacy of Rx drug supply to prevent sub-standard, adulterated, or counterfeit drugs

Challenges

Secondary Wholesalers

- Multiple WDs in History
- Falsifying Histories (First WD like Cardinal is False)
- Buying as a pharmacy, selling as a WD
- Affiliate transfers



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2012 Counterfeit Cancer Drug



PRESCRIPTION (LEGEND) DRUG PEDIGREE
History of Drug Sales and Distributions

Transaction Information:

Product Name include the strength and dosage form of the product and size of container:

Drug Name, Strength, Dosage Form

NDC	Qty	Date of Transaction:	Date of Shipment (if over 24 hrs)	Document ID
9-20	19	1/8/2016		

Lot Number:

Seller name and address

Buyer name and address

5. WD #4 NJ

6. WD #5 CA

Transaction History: (exempted if purchased directly from manufacturer.)

NDC	Qty	Date of Transaction:	Date of Shipment (if over 24 hrs)	Document ID
9-20	19	10/26/2015		

Lot Number:

Seller name and address

Buyer name and address

1. Manufacturer

2. Wholesaler #1 – Big 3 NY

NDC	Qty	Date of Transaction:	Date of Shipment (if over 24 hrs)	Document ID
9-20	19	10/26/2015		

Lot Number:

Seller name and address

Buyer name and address

Wholesaler 1 – Big 3 NY

3. Pharmacy (NH Contract). Co-located with WD. Same name, same address PA

NDC	Qty	Date of Transaction:	Date of Shipment (if over 24 hrs)	Document ID
9-20	19	10/26/2015		

Lot Number:

Seller name and address

Buyer name and address

3. WD #2 Pharmacy (NH Contract) Colocated with WD#2. Same name, same address PA

4. WD #3 NJ

NDC	Qty	Date of Transaction:	Date of Shipment (if over 24 hrs)	Document ID
9-20	19	10/27/2015		

Lot Number:

Seller name and address

Buyer name and address

4. WD #3 NJ

5. WD #4 NJ

Product Information

Item Description: [REDACTED] 200MG TABS

NDC: [REDACTED]-01

Size: 100

Lot Number [REDACTED]

Item Number: [REDACTED]

Manufacturer: [REDACTED]

Expiration Date: 06/30/2018

Transaction Information**Sold By:**

Wholesaler # 5 OH

Sold To:

Wholesaler # 6 CA

Transaction Date: 04/11/2016

Shipping Date: 04/11/2016

Quantity Shipped: 1

Transaction History

Owner Name	Address	Transaction Date	Reference#
Wholesaler # 4 KY		02/08/2016	[REDACTED]
Wholesaler # 3 NJ		01/18/2016	
Wholesaler # 2 co-located with Pharmacy License same name, same address PA		01/15/2016	
Pharmacy (Nursing Home Contract Price) co-located with WD License same name, same address PA		01/15/2016	
Wholesaler # 1 (Large, but not Big 3) NJ			
MANUFACTURER			

Transaction Statement

[REDACTED] here
(D), (E), (F) and (G). Please

A Section 581(27)(A), (B), (C)
provided [REDACTED] with a

Transaction Statement. Should you have any questions about this pedigree, please contact [REDACTED]

Future Issues

- Supply chain remains vulnerable to unscrupulous players
- Sec 582 Waivers, Exceptions, and Exemptions
- 2D Counterfeit Susceptibility
- Serial Number database/control, retirement, sharing, access



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