



California's E-Pedigree Law

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Statutory Mandate

- Protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

How did each get to pharmacy?

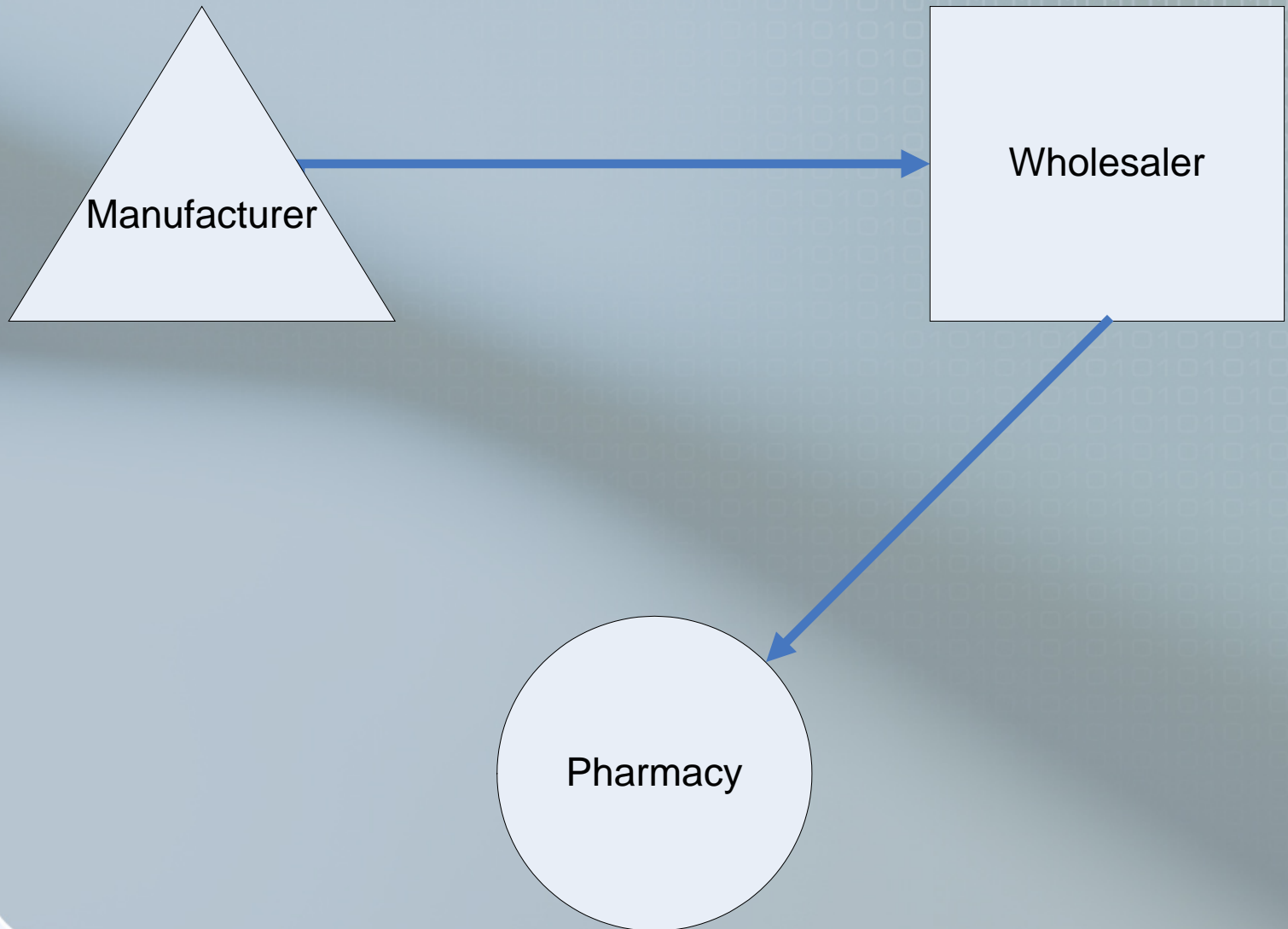


■ Pedigree

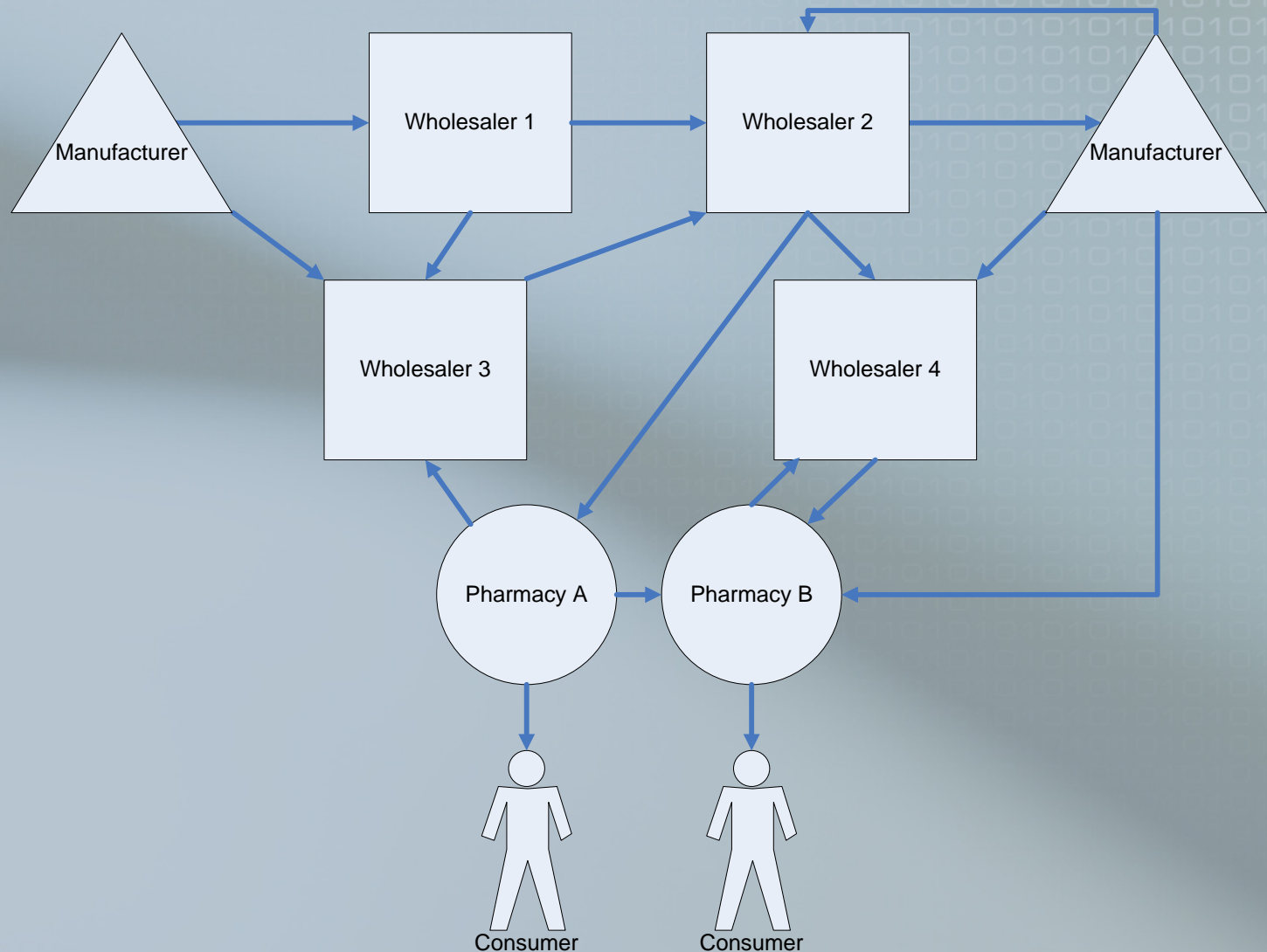
Today's Message(s)

- In California, firm deadlines of 2015-17 exist in law for manufacturers, wholesalers, pharmacies
- E-pedigree has been a long time coming – more than 20 years at the federal level, more than 8 years in California
- Serialization required for pedigree is not easy, takes time to perfect.
- Pedigree law applies to nearly all drugs.

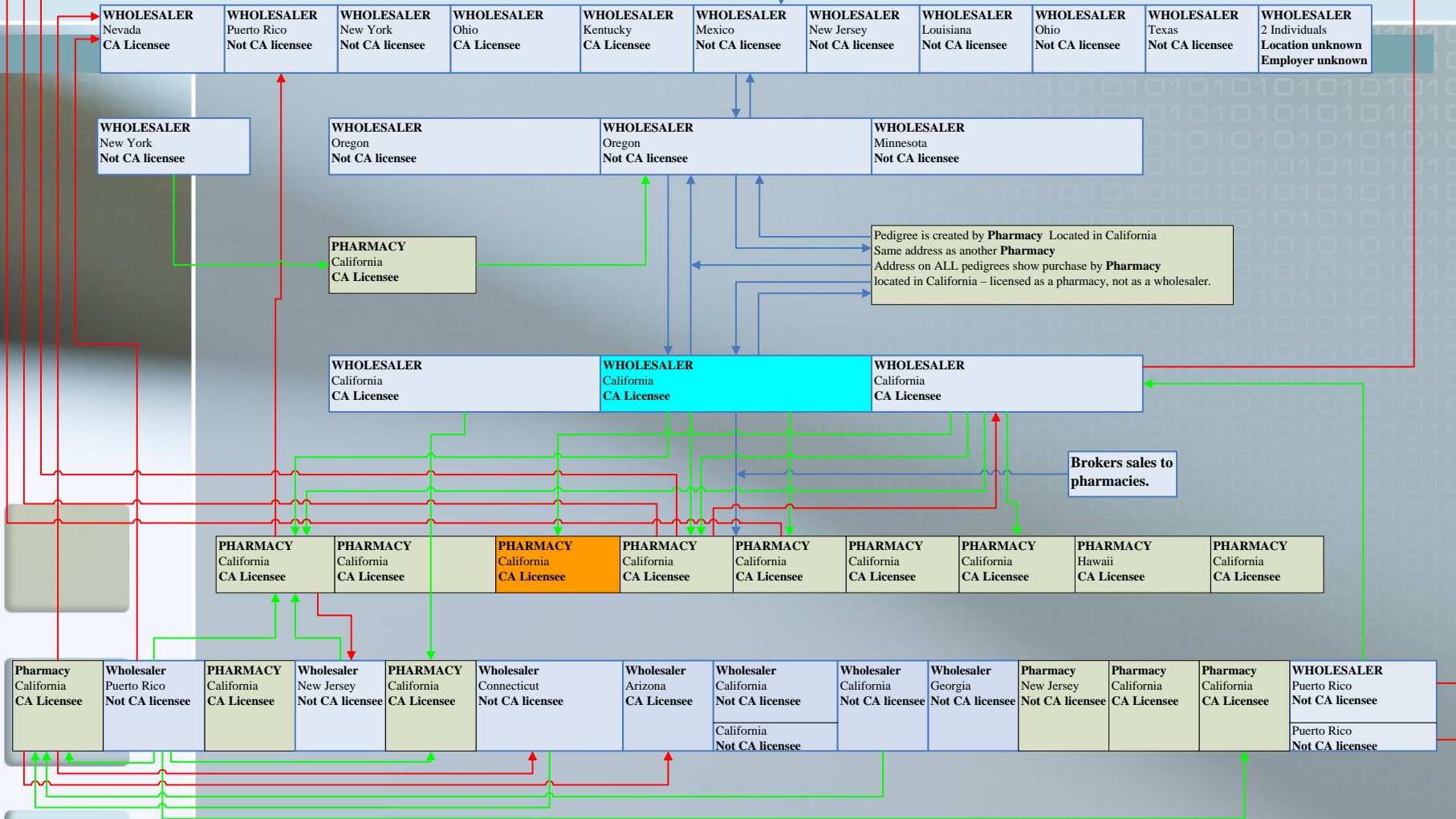
Pharmaceutical Supply Chain



Another Derivation of the Supply Chain



**Wholesale Broker Z: Unlicensed California Wholesaler
Arranges Sales & Purchases Through the Following**



How did each get to pharmacy?



■ Pedigree

Purpose of Pedigree

- The pedigree is an important part of a series of provisions intended to address threats to the prescription drug supply from counterfeit, misbranded, adulterated or diverted drugs. The overall intent is to secure the drug distribution system and sustain and increase confidence in authenticity of prescription drugs in California

Pedigree Definition

- “Pedigree” means a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition(s) and sale(s) by one or more wholesalers, manufacturers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering or dispensing the dangerous drug.

Pedigree Definition

- Pedigree shall be created and maintained in an interoperable electronic system, ensuring compatibility throughout all stages of distribution

Legislative Intent (2008 Legislation):

California's electronic pedigree system will "provide tremendous benefits to the public and to all participants in the distribution chain. Those benefits should be made available as quickly as possible through the full cooperation of prescription drug supply chain participants. To this end all drug manufacturers and repackagers are strongly encouraged to serialize drug products and initiate electronic pedigrees as soon as possible, and all participants in the supply chain are encouraged to immediately ready themselves to receive and pass electronic pedigrees.

Legislative Intent cont.

At the same time, it is recognized that the process of implementing serialized electronic pedigrees for all prescription drugs in the entire chain of distribution is a complicated technological and logistical undertaking for manufacturers, wholesalers, repackagers, pharmacies, and other supply chain participants. The Legislature seeks to ensure continued availability of prescription drugs in California while participants implement these requirements."

Interoperable electronic system defined

- Electronic track and trace system for prescription drugs
- Uses unique identification number
- Established at point of manufacture
- Contained within standardized non-proprietary data format and architecture
- Uniformly used by manufacturers, wholesalers and pharmacies

Electronic Pedigree Requirements

- Prescription Drug Information
- Transaction and Source Information
- Ownership Information
- Certification



Historical Context

- Origins of California's e-pedigree requirements lie in the post 1988 PDMA -- which did not stem diversion or counterfeiting. Publication of final regulations implementing PDMA (as amended by the Prescription Drug Amendments of 1992 (PDA)) in 1999.

Historical Context

- Pedigree regulations stayed repeatedly.
Rising concern over counterfeiting leads FDA Commissioner Mark McClellan to establish Counterfeit Drug Task Force in July 2003.
- Beginning in 2003, states spurred to act.

Historical Context

- In 2004, FDA Counterfeit Drug Task Force Report
 - Restated threat from recent increase in and sophistication of counterfeits/counterfeiters.
 - Among other findings, Report concluded that adoption and common use of reliable track and trace technology based on RFID tagging of products was feasible for use by 2007.
 - Encouraged use of electronic track and trace technologies and electronic pedigrees.

Historical Context

- Recommended universal pedigree requirement (not just non-ADRs) to document all drug movements.

STREET VALUE OF SOME CONTROLLED SUBSTANCES

- Dilaudid 4mg \$15-\$20 per tablet
- Fentanyl - \$10 per patch
- Hydrocodone - \$1 - \$5 per tablet
- methadone - \$10 per tablet
- methylphenidate - \$5 per tablet
- morphine - \$30 per/10 tablets
- MS Contin 60mg - \$20 per dose
- Oxycodone 80mg - \$12 - \$40 per tablet
- Oxycontin 80mg - \$35 - \$50 per tablet
- promethazine & codeine – LA - \$200 - \$300 / pint
- Tussionex - \$30 - \$40 per pint
- diazepam 5mg - \$1 - \$2 per tablet
- Vicodin ES - \$5 per tablet
- Xanax 4mg - \$3 -\$5 per tablet

** National Prescription Drug Threat Assessment 2009- California*

Diversion from Supply Chain

- 100,000 tablets of Vicodin stolen by ordering technician from a San Diego hospital and no one at hospital knew until police arrested technician
- Technician at a children's hospital stole by ordering 250,000 Vicodin during one year – a drug not even used in the hospital
- 50,000 tablets of generic Vicodin stolen from a retail pharmacy by trusted technician. Pharmacy had no idea drugs were missing

More Diversion

- Pharmacy refill center for 18+ stores lost 330,000 Vicodin
- One chain store lost 220,000 Vicodin during 18 months

Diversion via Drug Thefts

- Manufacturing
 - Eli Lilly Warehouse - \$75 million
 - Eli Lilly truck - \$37 million
 - Teva truck - \$11.8 million
 - Novo Nordisk truck - \$11 million
 - Astellas truck - \$10 million
 - Unknown company - \$8 million
 - GSK Warehouse - \$5 million
 - Exel Distribution Center - \$3 million
 - Dey Pharmaceuticals 2 trucks - \$2 million each
- *CBI Bio/Pharmaceutical Summit on Finished Product Supply Chain

Pharmacy Related Criminal Activity

- Criminals know:
 - Profit high with prescription drug diversion
 - Chances of prosecution reduced if caught
 - Sentences related to prescription drug convictions are less than distribution of illegal drugs
 - High demand on street for pharmaceuticals diverted from a pharmacy

Recalls

- Today there are an ever increasing number of recalls
- During 2010-11, 162 recalls at the pharmacy or patient level
- Between July 18 and 22, 2011, there were 10 recalls at the pharmacy or patient level, specifically:

Recalls 7/18-22/2011

- Pierre Fabre Pharmaceuticals (7/18)
- RX PAK (7/18)
- King Pharmaceuticals (7/18)
- Bedford Laboratories (7/18)
- APP Pharmaceuticals (7/18)
- Bausch & Lomb (7/19)
- Lupin (7/20)
- Teva (7/20)
- Bedford (7/20)
- American Reagent (7/22)

Why are Recalls a Problem?

- California identified a serious problem with the removal of recalled products from a pharmacy's control

Resolution:

- Citations and fines for pharmacies and pharmacists-in-charge
- Statutory changes in California law (7/2009) to require all licensed sites to join Board's subscriber alert to enable immediate contact of licensees
- *Recall Best Practices* for hospitals developed in series of meetings with stakeholders
- Board will share and route recall notices

Drug Shortages

- Opportunities for some to make big money
- Desperate pharmacies, hospitals and prescribers resort to purchasing drugs from unlicensed suppliers, without knowing who they are dealing with
- Hoarding, skyrocketing prices, shortages, desperate patients

So, why pedigree needed?

- Drug diversion because of high value of prescription drugs
- Drug thefts from supply chain
- Low penalties if prosecuted
- Recalls
- Drug Shortages
- Are there still counterfeits/ adulterated/misbranded drugs?

Problems Uncovered in CA

- **2010 Med error investigation triggers identification of a counterfeit drug in a chain store pharmacy purchasing from one of the big three. Low cost brand name drug**
- **Fall 2010 Canadian drugs being dispensed in US by pharmacies -- no NDC, just DIN**
- **Overly complex drug distribution makes investigation involving diversion and counterfeiting difficult** (28 wholesalers, 21 non-licensed in CA; 17 pharmacies; one wholesale broker overseeing all)

California's Response

- E-Pedigree Requirements for all prescription drugs that will be sold in California

CA Pedigree Requirements – 2008 and After

Sequenced implementation and the compliance timeline has been moved out

- **Manufacturers (generic and brand) must pedigree:**
 - 50 percent of their products by 2015,
 - the remaining 50 percent by 2016
- **Wholesalers and repackagers must accept and pass pedigrees by July 2016**
- **Pharmacies and pharmacy warehouses must accept pedigrees by July 2017**
- **Percentages can be based upon:**
 - Unit volume
 - Product package (SKU) type
 - Drug product family

CA Law (2008 legislation):

Exemptions:

- Radiologic drugs
- Drugs labeled “for veterinary use only”
- Compressed medical gases
- Solutions:
 - IV solutions for replenishment
 - IV solutions used to maintain equilibrium of water and minerals (dialysis)
 - Solutions for irrigation or reconstitution
- Surgical kits containing a device and medical supplies, sealed by the Mfg.
- Kits containing a drug/device, biologic/device, drug/biologic/device that are physically or chemically or combined as produced as single entity
- Kits containing two or more products packaged together in a single package comprised of a drug and device or biologic and device
- Drugs received by a state or local government agency from a federal govt. agency

CA Law (2008 legislation):

Expanded or new definitions:

- Manufacturer includes NDA, ANDA, and BLA holders; contract Mfgs
- “Smallest package or immediate container” which must be pedigreed is further defined as the smallest unit made by the mfg. “for sale to the pharmacy”
- Third party logistics provider: a licensed wholesaler who takes possession of, but not ownership of, drugs. Does not need to append pedigree but must maintain copies of it.
- Invoice Annotation to Pedigree: allows a customer-specific shipping number referenced to the sales invoice number in place of invoice number

CA Law (2008 legislation):

“Repackager” added to various sections to clarify that repackagers are:

- a manufacturer that must pedigree repackaged items
- Must reference original pedigree information on repackaged products
- Must create a unique identification number for pedigree of repackaged items

CA law (2008 legislation):

Inference

- Board to establish regulations
- Allows a unique identifier to be applied to a case, pallet or other “aggregate” without individually reading each serialized unit
- Specifies intent that Mfgs, wholesalers and pharmacies distribute and receive electronic pedigrees, and verify and validate pedigrees at the unit level except where efficiency and safety can be secured through inference

CA Law (2008 legislation):

Grandfathering

- Establishes process for mfgs., wholesalers and pharmacies to designate drugs already in their possession when pedigree requirements kick in
- Exempts from pedigree requirements drugs described in written lists submitted to board
- These lists are confidential
- Board may establish requirements for the lists -- regulations

CA Law (2008 legislation):

Drop Shipment

- Provides definition: Products shipped from Mfg to Pharmacy; Ownership/Pedigree goes from Mfg to wholesaler to pharmacy
- Regulations may be developed to establish alternative pedigree

Reporting Counterfeits in CA

- If a manufacturer, wholesaler or pharmacy has reasonable cause to believe that a dangerous drug in, or having been in, its possession is counterfeit or the subject of a fraudulent transaction, the manufacturer, wholesaler or pharmacy shall notify the Board within 72 hours of obtaining that knowledge. This subdivision shall apply to any dangerous drug that has been sold or distributed in or throughout CA

CA Business & Prof Code 4034(h)

Senator Ridley-Thomas' Letter to the Senate Journal (8/25/08)

- Commemorating agreements that the amendments incorporated in SB 1307 by all involved parties to operate in good faith to implement the requirements as soon as possible and by the dates established in the bill. Writing in support are:

- | | |
|-------------------------|-----------------------------|
| ■ Abbott Laboratories | Biocom |
| ■ Amgen | CA Healthcare Institute |
| ■ Arena Pharmaceuticals | CA Pharmacists Association |
| ■ Barr Pharmaceuticals | CA Retailers Association |
| ■ Baxter Healthcare | CA Society of Health-System |
| ■ Bayer Healthcare | Pharmacists |

Entities in Support (cont)

- CA State Association of Counties
- Cardinal Health
- Compressed Gas Association
- Council on Radionuclides and Radiopharmaceuticals
- Daiichi-Sankyo
- Genentech
- Generic Pharmaceutical Association
- Gray Panthers
- Healthcare Distribution Management Association
- Hospira
- Johnson and Johnson
- McKesson Corporation
- Merck, Inc.
- Mylan, Inc.
- National Association of Chain Drug Stores

Entities in Support (cont)

- National Coalition of Pharmaceutical Distributors
- Novartis Pharmaceuticals
- Pfizer
- Pharmaceutical Research and Manufacturers of America
- Rite Aid
- Sandoz, Inc.
- Teva Pharmaceuticals, USA
- Walgreens
- Wyeth

In the future

- Federal Legislation?
- CA Board of Pharmacy will begin developing regulations regarding
 - Inference
 - Decommissioning
 - Drop Shipment Pedigree
 - Grandfathering Lists
 - Linkage between invoice and shipping notice

Meetings:

- September 7, 2011 – Board Meeting, Los Angeles
- December 6, 2011 – Enforcement Committee, Sacramento
- Calendar for 2012 Established
March 13, June 12, Sept. 11, Dec. 4
- Join our subscriber alert by going to www.pharmacy.ca.gov

How Will E-pedigree Help?

- Harder for stolen drugs to re-enter supply
- Recalls, returns, drug take-backs will be greatly facilitated by e-pedigree, will help end fraud
- Regulators will have the information they need to secure discipline of those who divert or purchase counterfeits

Questions?

Thank you

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