Safeguarding the U.S. Pharmaceutical Supply Chain: Industry efforts to further secure the supply chain

November 2010

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Agenda

• Supply Chain Integrity Is Critical?
• Legislation
• Pilots
Overview

- Advancing the healthcare industry for more than 176 years.
- Innovation, technology and process knowledge gives our customers and partners the power to succeed
- A leader in the distribution of pharmaceutical, medical surgical and specialty drugs
- Fortune 15 company, 3rd largest company in California with sales of $110 Billion.
LAST month, thieves cut through the roof of an Eli Lilly warehouse in Enfield, Conn., shimmied down a rope, disabled the alarms and made off with $75 million worth of psychiatric drugs, including the antidepressants Prozac and Cymbalta and the antipsychotic Zyprexa. It is thought to have been the largest pharmaceutical theft in history.

Without track-and-trace technology the only way a manufacturer can retrieve stolen drugs is to recall all the packages in the affected lot number, but that may include thousands when only a few hundred have been stolen. Manufacturers are understandably reluctant to issue such large, costly recalls.
Supply Chain Integrity Is Critical

- International legislative and regulatory agencies have concerns about the Pharmaceutical Supply Chain’s ability to effectively protect products
  - Expiration Date Handling
  - Cold Chain Management
  - Returns Processing
  - Recall Management
  - Tainted Products (Counterfeit and Mislabeled)
  - Ability to focus on specific units from a stolen lot

- A single weak link in the supply chain means we ALL fail
- We need to be knowledgeable about the products we buy
- We need to have our electronic systems capture and validate the information, and provide actionable information to the staff
Manufacturer

- January 1, 2015 50% of Drugs Serialized
- January 1, 2016 All Drugs Serialized

Wholesalers

- July 1, 2016 Wholesalers may not acquire, sell, trade or transfer pharmaceutical drugs without a pedigree

Providers (Pharmacies and Hospitals)

- July 1, 2017 Pharmacies may not acquire, sell, trade or transfer pharmaceutical drugs without a pedigree

- Inference through aggregating units to a case
- Grandfathering
- Federal legislation would preempt CA requirement
It is expected that next year “Safeguarding America’s Pharmaceuticals Act,” will be re-introduced to provide a uniform federal pedigree standard.

- Uses California’s Phase-In Approach
- Preempts state laws on serialization and pedigree
- Standard supply chain definitions across all states
- Standard pedigree requirements
- Standardized drug identifiers
Progress on Serialization / Pedigree

- FDA published the guidelines for Serialized Numerical Identifier (SNI) in March 2010 as required by the FDA Amendments Act.
- A small number of manufacturers in the US have moved forward with Serialization / Pedigree projects
- McKesson is currently working with 7 manufacturers to test:
  - RFID and barcode reads on pallets and cases
  - RFID and 2-D barcode reads on individual bottles
- GS1 and EPCglobal developing the standard for serialization and pedigree
Serialization and Pedigree Pilots

Pilots have three concepts to test:

- Serialization at the unit, case and pallet
- Inference (serialized units aggregated into a case and cases aggregated into a pallet)
- Pedigree data exchange

Types of tests conducted

- Data carrier validation (a new one)
- Matching physical product serialization to pedigree data

4 Wall Cold Chain

- Tracking Cold Chain product from opening inbound truck to storage in refrigerated environment
Questions?