

MCKESSON

Empowering Healthcare

Safeguarding the U.S.

Pharmaceutical Supply Chain:

Industry efforts to further secure the supply
chain

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SVP Distribution Support

- Supply Chain Integrity Is Critical?
- Legislation
- Pilots

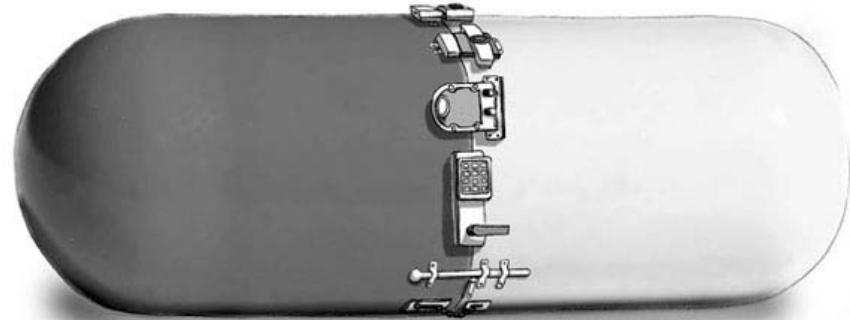
Overview

- 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.



OP-ED CONTRIBUTORS

Are You Buying Illegal Drugs?



Published: March 31, 2010

LAST month, thieves cut through 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**

State of California ePedigree

➤ **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

- ▶ Key Provisions of the Bill:
 - 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?