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Counterfeit Drugs: Working to Enhance Patient Safety

August 11, 2009
Pharmacy & Technology Conference

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Security for the Drug Distribution Supply Chain

- » 1988 - Prescription Drug "Pedigrees" (PDMA)
 - » State laws –
 - Pedigrees for wholesale distributions outside normal distribution channel
 - Increased requirements for wholesale drug distributors
 - » 2007 FDAMA – FDA to develop
 - standard identifiers for prescription drugs
 - Standards for tracking Rx drug distribution

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What is a "pedigree"?

- » FEDERAL = PDMA

A statement that unauthorized distributors (non-ADRs) must provide to the purchaser that identifies each prior sale or distribution of the prescription drug

 - Commonly called a "pedigree"
 - "Pedigree" term not used in Federal law
 - Drug manufacturers and ADRs not required to provide pedigrees
- » STATES =
 - different pedigree definitions but same concept
 - Pedigrees for distributions outside the normal distribution channel

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Federal PDMA vs State Pedigree Law

<p>PDMA</p> <p>Pedigrees required for wholesale distributions by Non-ADRs</p> <p>ADRs can distribute drugs to other wholesalers & other purchasers with no requirement to provide pedigree</p>	<p>STATE</p> <p>Pedigrees for wholesale distributions outside the normal distribution channel</p> <p>ADRs that sell drugs outside the normal distribution channel must provide pedigree including sales to other wholesalers & ADRs</p>
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FDA ACT 2007

FDA Amendments Act of 2007

- Standards and identify effective technologies to secure supply chain against counterfeit drugs
- Standardized numerical identifier by March 2010
 - Manufacturers apply at package or pallet
 - Sufficient for identification & track & trace
- Standards to address promising technologies e.g. RFID, nanotechnology, encryption, and other track and trace or authentication technologies

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Federal Pedigree Legislation

- » Buyer-Matheson Discussion Draft 2008
 - Interim until Track and Trace
 - Drug Manufacturer packing list
 - Two types of pedigrees
 - Direct purchase from manufacturer
 - Standard i.e. full pedigree
 - Drug returns – no pedigree if not required by FDA
 - Pre-emption of states pedigrees &T&T
 - Rx drugs track & trace
 - Std identifier on all drugs by Jan 2016
 - Wholesalers starting July 2016
 - Pharmacies & other dispensers by July 2017

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State Pedigree Laws

- » 32 states – pedigree laws
- » 2009 → Pedigree bills in MA, NY and PA
- » Different state approaches:
 - CA – electronic track and trace
 - Wholesalers T&T by July 2016
 - Pharmacies/pharmacy warehouses by July 2017
 - FL – electronic pedigrees

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Diane Darvey, Pharm.D., JD
 Director Public Policy
 NACDS
 ddarvey@nacds.org

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