



Application of Track & Trace Technologies to Containers

New England PDA (NEPDA)

September 17, 2008 Burlington, MA

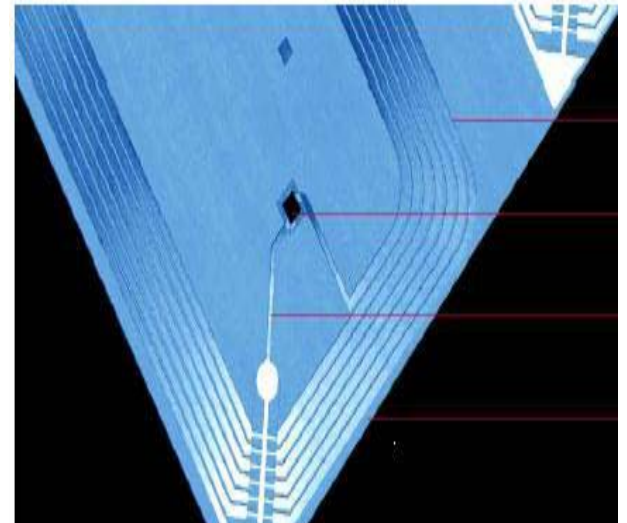
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Personal Background

Over 25 years of experience in the Pharmaceutical Industry with E. R. Squibb & Sons, Bristol - Myers Squibb and Bracco S.p.A. in the area of drug development and global development strategies for product packaging.

Founder and Principal Consultant

Eakins & Associates

International Consultants to the Medical Components and Pharmaceutical Industries

Vice-Chair USP Packaging & Storage EC

Experience in Anti-Counterfeiting



- **Chair PDA Anti-Counterfeiting Forum, Bethesda (2006) & Berlin (2007)**
- **PDA Training Course for the Kazakhstan Ministry of Health, Bethesda (2007)**
- **U.S. – India Dialogue Pharmaceutical Anti-Counterfeiting Seminar: Building International Cooperation to Protect Indian Patients, New Delhi (2006)**
- **Presentations at International Conferences in Berlin, Bethesda, London, Paris, Philadelphia, Orlando & Tampa (2004 – 2007)**
- **Collaborated with OECD on their “Counterfeiting & Piracy of Pharmaceuticals” Report (D3Q/2008)**



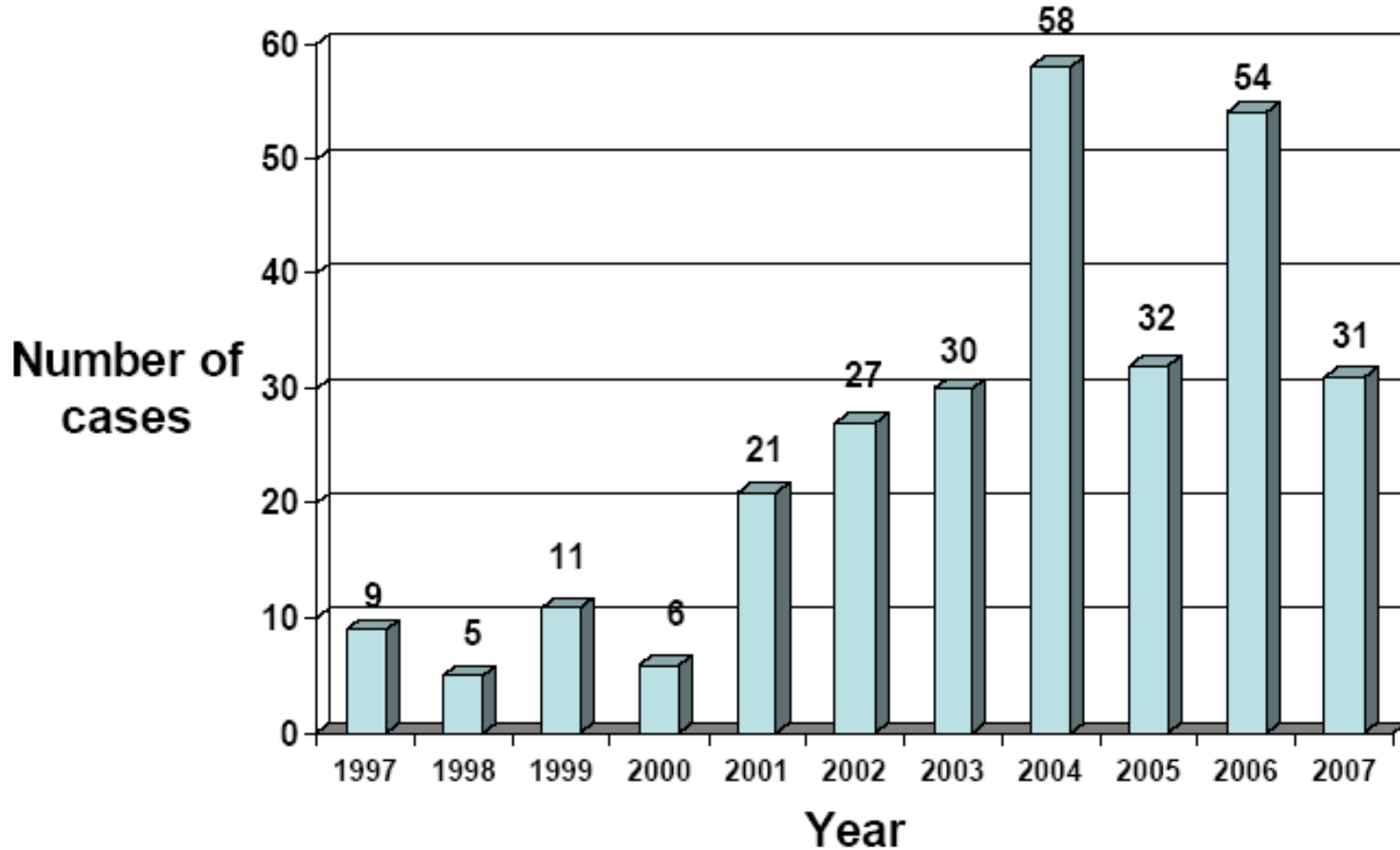
Application of Track & Trace



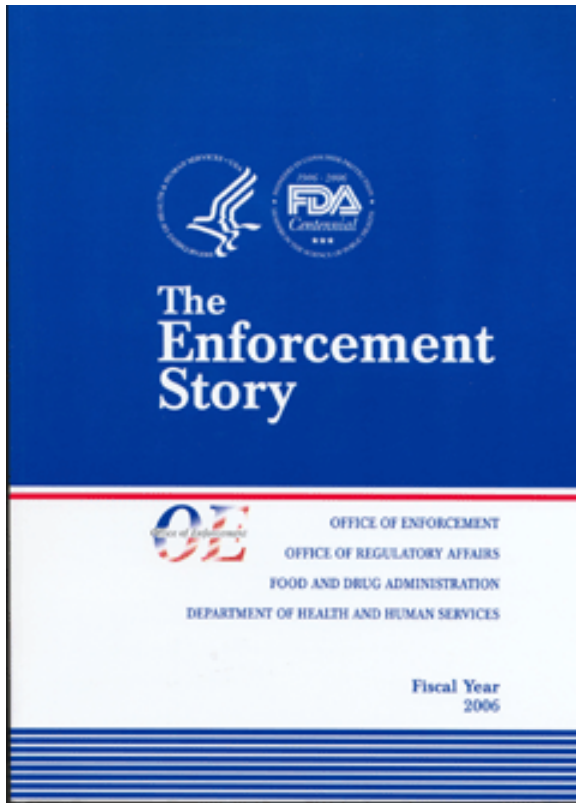
- **Threat to USA**
 - **Magnitude**
- **A-C Initiatives**
 - **FDA, States**
- **Technology**
 - **RFID**
 - **2D Bar Codes**



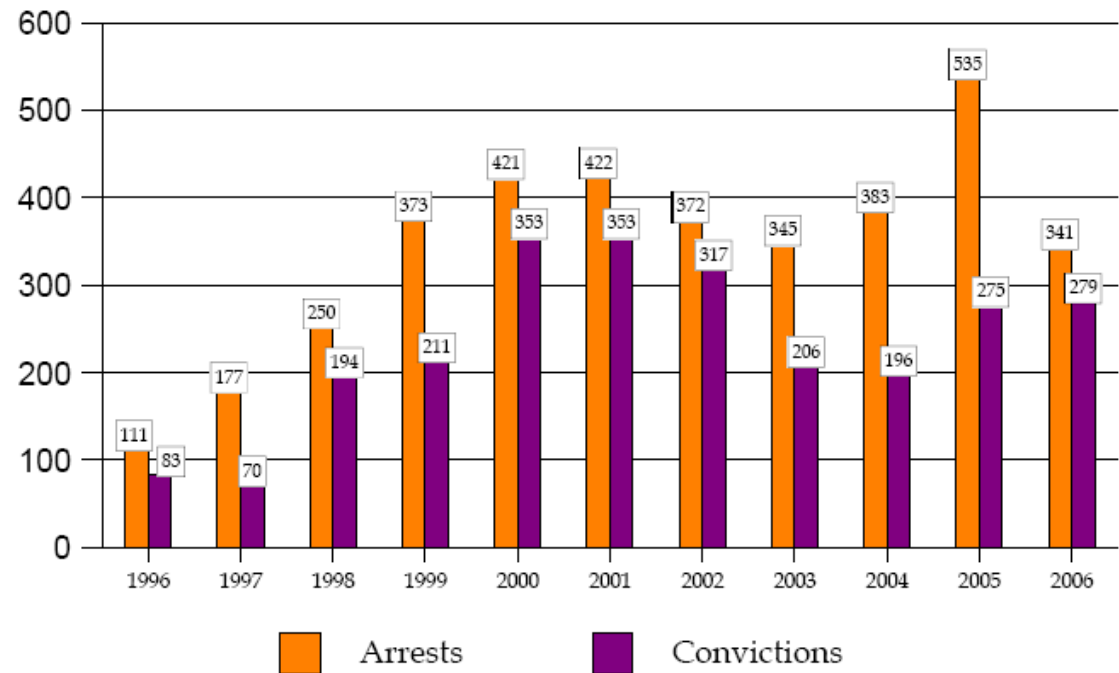
Counterfeit Drug Cases Opened by FDA per Fiscal Year



FDA Office of Criminal Investigations



Office of Criminal Investigations
Fiscal Years - 1996 - 2006





FDA Office of Criminal Investigations

Statistics for 2007

- **OCl opened 31 investigations on counterfeit drug products**
- **Led to 71 Arrests**
- **50 Convictions**
- **> \$26.5 M in fines and restitution**



Counterfeit Drugs in USA

- **High Priced Drugs – Often Injectable Products**
- **High Volume, Name Brand, Widely Prescribed Drugs – Pharmacy Dispensed**
- **“Lifestyle” = ED, Diet, Sports Doping Drugs – Internet Sites, Black Market Sales**



Examples of Counterfeit Drugs in USA (2001 – 2004)

- Gamimune[®] N (Biologic)
- Neupogen[®] (Biologic)
- Nutropin AQ[®] (Biologic)
- Epogen[®] (Biologic)
- Procrit[®] (Biologic)
- Serostim[®] (Biologic)
- Combivir[®] Tablets
- Lipitor[®] Tablets
- Viagra[®] Tablets





Magnitude of Threat to the USA

About 4 billion prescriptions were filled in USA in 2005

FDA estimates that only “significantly less than 1% were counterfeit”

Reliable estimates “impossible”



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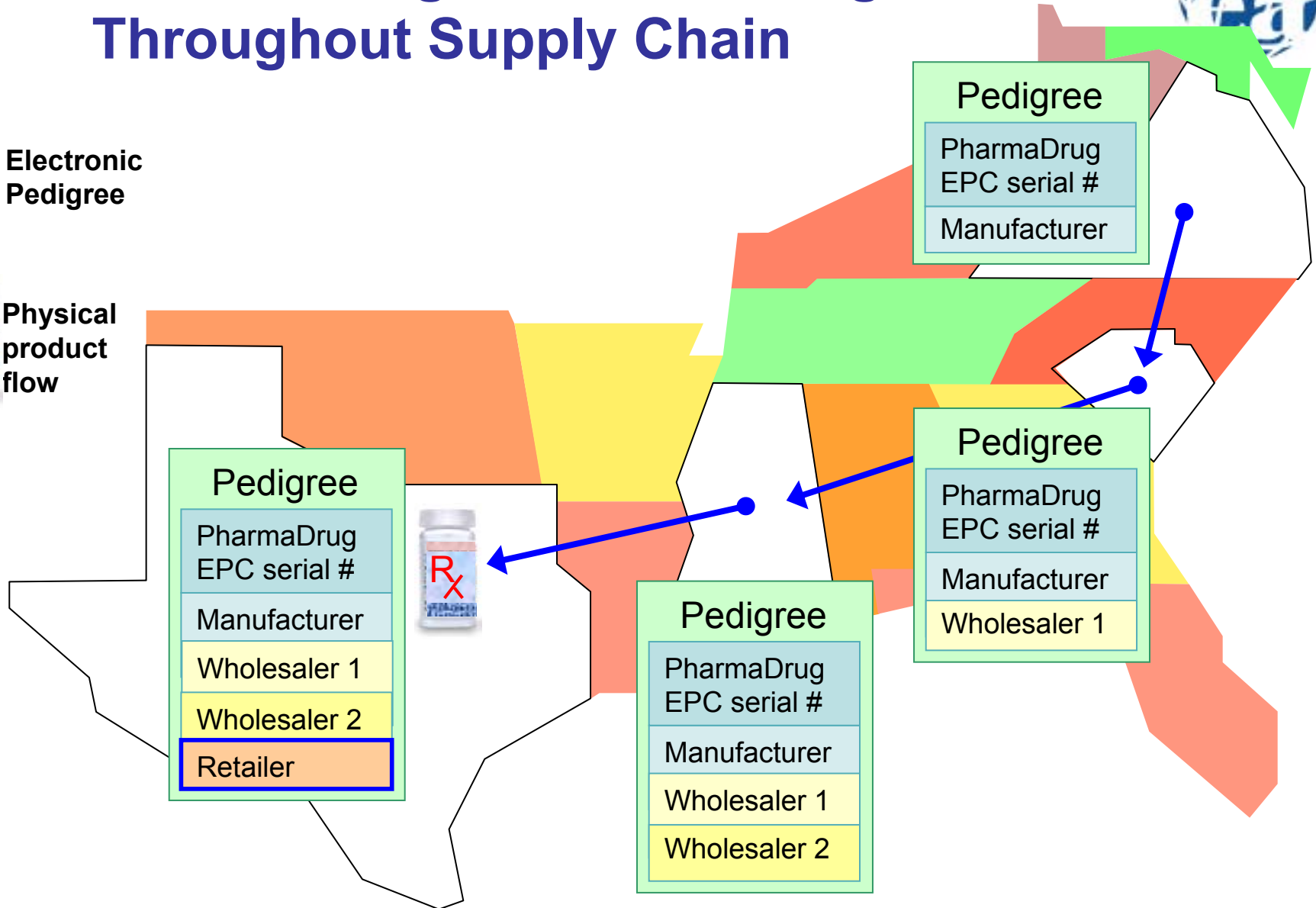
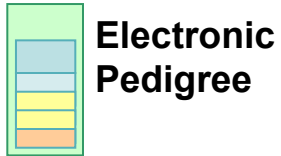
1987 Prescription Drug Marketing Act



Key Provisions include:

- A requirement that wholesale distributors of prescription drugs who are not authorized distributors provide a statement of origin, also known as a drug “pedigree” to each wholesale distributor. The pedigree traces each prior sale, trade, or purchase of the prescription drug.

Electronic Pedigree Tracks Drug Throughout Supply Chain



1987 Prescription Drug Marketing Act



- **Section 203.3(u) defines "ongoing relationship" to include a written agreement between manufacturer and wholesaler**
- **Section 203.50 specifies the fields of information that must be included in the drug pedigree and states that the information in the pedigree should be traceable back to the first sale by the manufacturer**

1987 Prescription Drug Marketing Act



FDA delayed implementation of 21 CFR 203.3 (u) and 203.50 in 2001, 2003 & 2004 until 12/1/2006

- **The National Coalition of Pharmaceutical Distributors and companies e.g. RxUSA, obtained a temporary injunction in Federal Court to delay implementation of PDMA, November 2006**
- **FDA failed to get injunction overturned on appeal**
- **FDA Options: Continue Appeals; Litigate; Await Congressional Action e.g., H.R. 5839 “Safeguarding America’s Pharmaceuticals Act of 2008”**

FDA Amendment Act 2007 (H.R. 3580-131)



Section 505D Pharmaceutical Security

- 2) **Standardized Numeral Identifier - implement by March 2010 for prescription drugs from point of manufacturing and repackaging**

- 3) **Promising Technologies – The standards developed shall address promising technologies, which may include-**
 - (A) **Radio-frequency identification technology**
 - (B) **Nanotechnology**
 - (C) **Encryption technologies**
 - (D) **Other track & trace or authentication technologies**

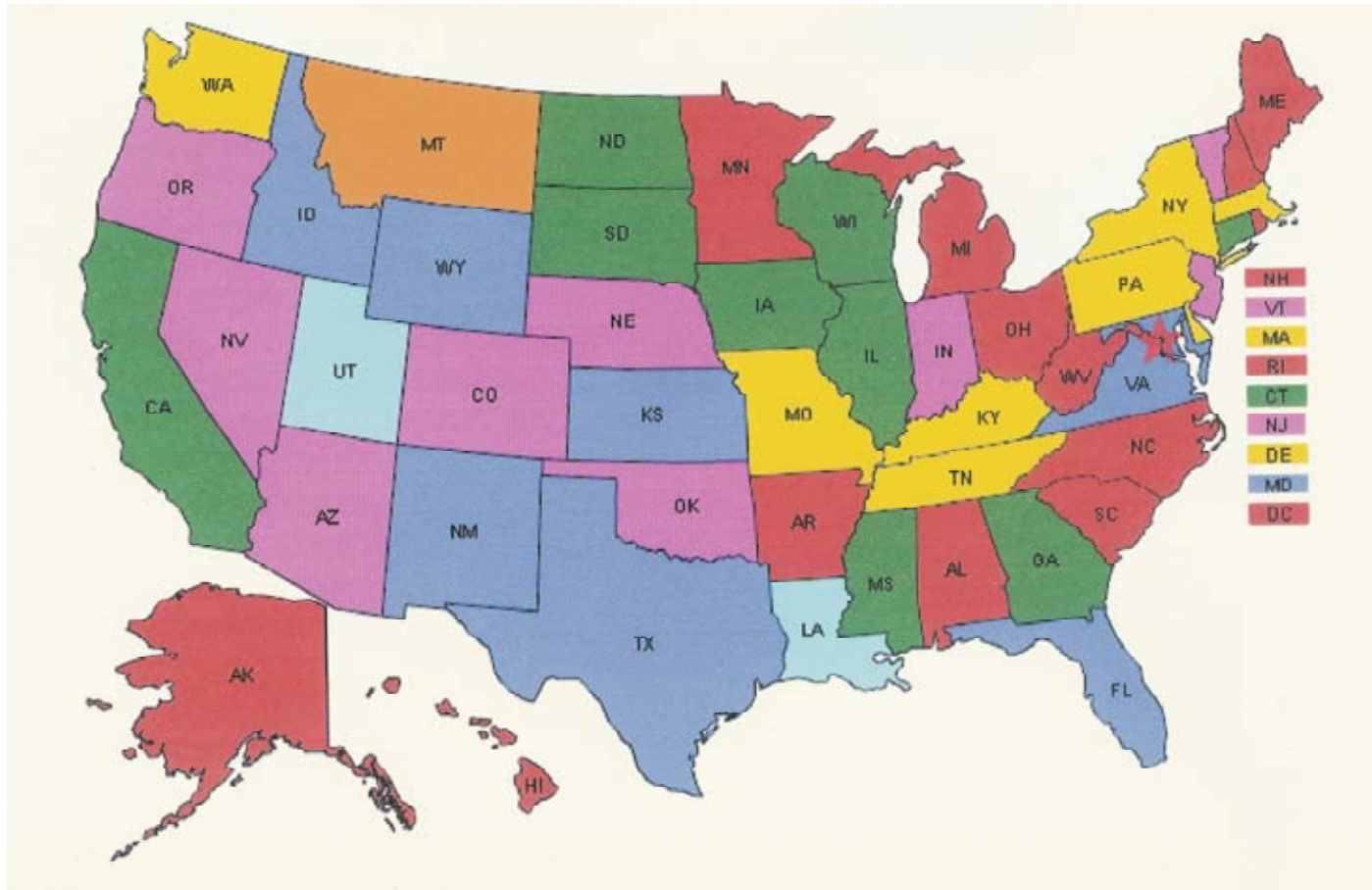


Universal Pedigree and Uniform Pedigree Fields

Ten States (CA, FL, IN) have laws imposing pedigree requirements not covered under the PDMA – additional or different information

- FDA agreed that a single, national, uniform pedigree would be ideal – 50 different requirements would cause confusion and stifle inter-state trade**
- FDA lacks statutory authority to implement a universal and nationally uniform pedigree**

US State Drug Pedigree Legislation / Regulations (December 2007)



Slide: Healthcare Distribution Management Association



FDA Anti-Counterfeit Initiative 2004

RFID Adoption Potential Timeline:

2004 Mass serialization feasibility studies using RFID on pallets, cases & packages of drugs

2005 Mass serialization of some pallets, cases & packages of drugs likely to be counterfeited

Acquisition and use of RFID technology by some manufacturers, large wholesalers, large chain drug stores and hospitals

FDA Anti-Counterfeit Initiative



RFID Adoption Potential Timeline:

2006 Mass serialization of MOST pallets, cases & packages of drugs likely to be counterfeited and some pallets and cases of other pharmaceuticals. Acquisition and use of RFID technology by MOST manufacturers, large wholesalers, large chain drug stores, hospitals and some small retailers

2007 Full implementation

FDA Counterfeit Drug Task Force Report – 2006 Update



Progress in Use of E-Pedigree:

- **Implementation of RFID by 2007 will not be met**
- **RFID remains the promising technology for track & trace although the same goals can be achieved by other technologies such as 2-D Bar Codes**
- **Most likely scenario is a transition period which uses a hybrid, i.e. paper & electronic pedigrees**
- **Cited obstacles and concerns to implementation of RFID**

Obstacles Cited to Rapid Adoption of RFID



- **Lack of standards (for e-pedigree fields and format, data systems, international standards, hardware specifications)**
- **Challenges in serializing all products**
- **Concerns over accuracy and speed of electronic devices and systems**
- **Concerns over privacy and data ownership**
- **Lack of data on effect of RFID on sensitive products (liquids, biologics)**



FDA Recommendations

- **Stakeholders continue moving forward in implementing RFID across the supply chain**
- **Stakeholders consider a phased-in approach, initially placing RFID tags on products most vulnerable to counterfeiting and diversion**
- **FDA remain committed to facilitating RFID implementation**

RFID Technical Issues



Data Security and Privacy Issues:

- Safeguards needed
- Concern over security of RFID tag data base
- Presence of RFID tag should be clearly indicated by text or symbol (to be developed)
- Consumer education as to benefits
- When and how to “turn off” an RFID tag



Tag Turn Off

Who and When

- **Last person in the Healthcare Professional Chain – e.g. Doctor, Nurse, Pharmacist?**
- **The Patient?**
- **No protection against criminal healthcare professionals**

Potential RFID — Drug Interactions



Does RFID impact the quality, safety or efficacy of pharmaceuticals & biopharmaceuticals?

- **Thermal effect on solid dosage forms**
- **Non-thermal effects – impact on molecular bonds**

Recommendation: FDA to quickly complete its RFID Impact Study on drugs and biologics and publish the results



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Anti-Counterfeiting Technologies: Serialization/Track & Trace



Advantages	Disadvantages
High tech and secure against copying	Significant cost to implement and monitor
May be capable of remote authentication, via phone or internet	Difficult to implement across multiple markets
May be accessible to authorities and investigators without compromise	May be vulnerable to hackers
May eliminate dispensing errors	Damaged labels may not read

WHO IMPACT: Anti-Counterfeit Technologies for the Protection of Medicines

Anti-Counterfeiting Technologies: Serialization/Track & Trace



Advantages	Disadvantages
Facilitates recall of defective products	Robustness of RFID tags not proven
May combat theft and fraud	Needs harmonization of standards
Benefits in supply efficiencies	Not accessible to the public
	Remote reading causes privacy issues

WHO IMPACT: Anti-Counterfeit Technologies for the Protection of Medicines

Role of RFID in Pharmaceutical Industry



- **Gather data on product diversion**
- **Manage recalls**
- **Develop market intelligence**
- **Ensure patient safety**
- **Build a safe and secure supply chain**
- **Monitoring patient compliance in clinical trials**



Secondary Components: Cartons

- **Intelligent Pharmaceutical Packaging - Cerepak™ Electronic Compliance Packaging (MeadWestvaco)**
- **Records time/date dose is removed**
- **QOL Questionnaire – logs side effects**
- **Identifies non-compliance**



Cost of RFID in Pharmaceutical Industry



- **Research on potential effect on drugs – especially parenteral drugs**
- **Distribution Chain Pilot Studies**
- **RFID Tag & Reader Costs**
- **Regulatory Filings**
- **Data Storage – 5 years after end of shelf life**
- **New Labels**



E-Pedigree Options

Item Level

- ① 2D Data Matrix
- ② 2D Data Matrix
- ③ HF or UHF NF RFID

Case Level

- 2D Data Matrix
- UHF RFID
- UHF RFID

Option 1: Labor intensive for supply chain, needs line of sight, quickest

Option 2: Still complex to read item, case can be easy to read, item still line of sight

Option 3: Most costly, easier to read



Where to Place RFID Chips

EPCglobal Logo and RFID Tag location (tag is under label)



Within cavity of plastic bottle



Within Vial Seal





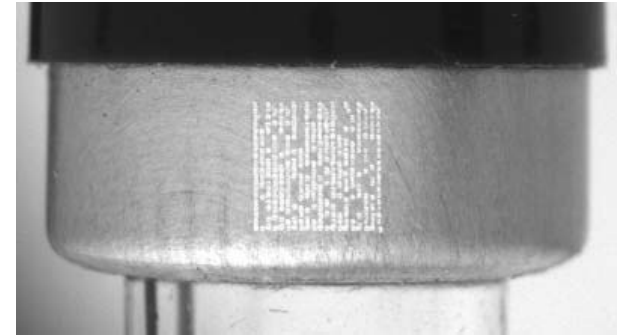
2D Bar Codes on Vials



Frewitt LAS



**ATS/Tesa
VALIDATE™**



**Nd-YAG laser
FP Developments
NJ, USA**

**Non Aggressive Glass
Internal Engraving
Laser System
(NAGINELS)**



Eakins & Associates

Application of RFID to Drugs in USA



- **Viagra[®]** — launched 1/2006. HF tags combined with redundant 2-D bar code at item level; UHF tags on cases and pallets
- **Celebrex[®]** — UHF tags on cases and pallets in 2007
- **Trizivir[®]** — UHF tags on cases and pallets and HF on item level in 2005
- **OxyContin[®]** — UHF tags on cases and pallets and item level in 2005
- **Fentora[®]** — Pilot study ongoing



RFID Tags on Contrast Media

- **Ultravist RF[®] & Magnevist RF[®] Bayer HealthCare**
- **Developed in conjunction VistaTrak – an RFID cabinet for hospitals to track contents and its use**
- **Optiray[®] — contrast media from Tyco HealthCare; tags on pre-filled syringes**



RFID Versus 2D Bar Codes: Europe



EFPIA Position Paper: Identification & Coding of Pharmaceutical Products in Europe, November 2006

GIRP Position Paper: Improving Patients' Safety Using Machine Readable Codes. Product Identification as a Basis for Tracking and Tracing, June 2006

- **Focus on currently available technology - recommended the 2 D Data Matrix barcode**
- **RFID could be adopted at a later date**



THANK YOU

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