

Healthcare & Life Sciences Business Action Group Update

Michael Rose
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Johnson & Johnson

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EPCglobal 



AGENDA

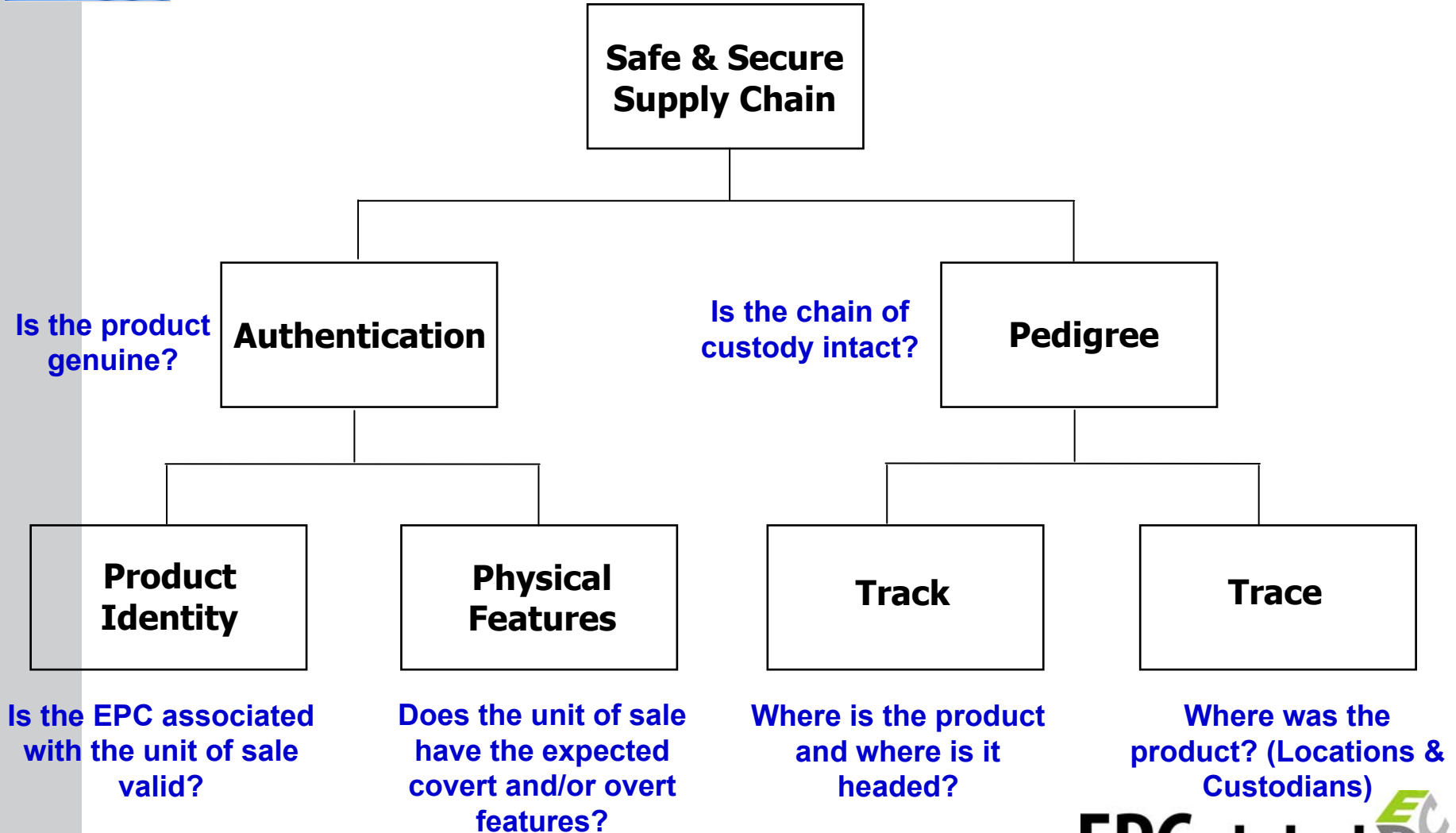
- Introductions – Michael Rose
- Overview of HLS BAG Activities – Bob Celeste
- Item Level Tagging Update – Chuck Schramek
- Pedigree Messaging Update – Ted Ng
- Panel Discussion on Joint Opportunities -- All

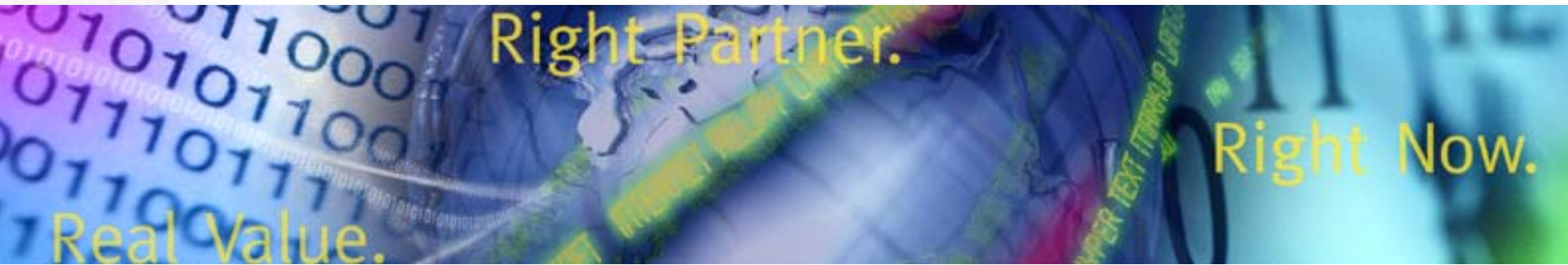


Emerging Regulatory Drivers

- Patient safety!
- FDA – track & trace of items
 - widespread adoption by 2007
- States – Pedigree regulations
- Ex US – Belgium, Italy, Taiwan, China
 - Serialization of items
 - Europe – pharmacy fraud

Base Reference Model





HLS BAG

Organization and Current Activities

Bob Celeste
Director, Action Groups
EPCglobal US



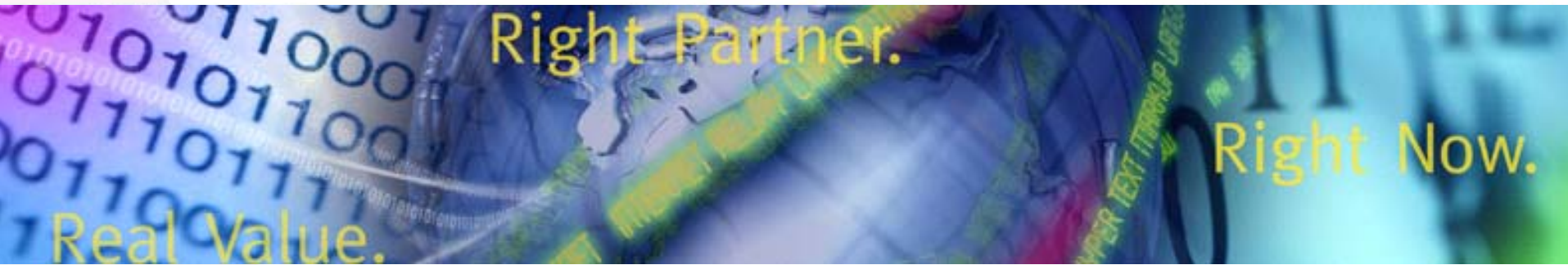
Healthcare & Life Sciences

- HLS Global Priorities
 - Item Level Tagging
 - Electronic Pedigree
 - Track and Trace
 - Product Authentication
 - Serialization
- Legislation for pedigree to prevent counterfeiting and diversion, product recalls (FDA and State).
- Initiatives seeking to control regulated prescription drugs and track controlled substances
- Participation from members, solution providers, agencies, trade associations



HLS '06 Roadmap – Chicago Results

	Group A	Group B	Group C	Group D
C-1	Track & Trace	Track & Trace	Track & Trace	Track & Trace
C-2	Reverse Logistics	Reverse Logistics	Reverse Logistics	Reverse Logistics
K-1	Decommissioning	Decommissioning	Decommissioning	Decommissioning
K-2	Security	Security	Security	Security
K-3	Authentication	Public Policy	End-to-End	Industry Adoption
P-1	Public Policy		Pilot program	HLS/HUG
P-2				X-Action Group



HLS BAG Item Level Tagging Joint Requirements Group Update

Chuck Schramek

Director, Action Groups

EPCglobal US

On Loan from Johnson & Johnson

EPCglobal 



Objectives of the ILT JRG

- Develop business requirements for an item level tagging specification:
 - **Business Scenarios:** positioning item level tag use
 - **Operating environments:** individual items in the supply chain
 - **Min/max ranges and rates:** tag read/write
 - **Security requirements:** general type, encryption strength and key management
 - **Privacy features:** including consideration of worldwide regulations
 - **Memory features:** including size and organization



ILTJRG Process – To Date

- Jan 13 – Final draft of Requirements & Business Scenarios delivered to HAG
 - ILTJRG Requirements Document – 32 pages spanning 60+ Scenarios
- Jan 16-17 – HAG, FMCG & HLS identified 7 critical scenarios to be demonstrated
 - Hanging Garments on Mobile Metal Hanger Rack
 - Dock Door Portal
 - Apparel Point of Sale
 - DVD in Adjacent Shelf Slots
 - Vial & Ampoules in Case
 - Retail Pharma Mixed Tote
 - Vial & Ampoule Write



Areas of Central Focus:

1. Performance Considerations

- Operation for Tags
- Operations Between Tag(s) and Reader(s)
- Operations of fixed Reader in Presence of Mobile Reader
- Operation in Dense Reader Environments

2. User Memory Considerations

- Amount of Memory
- Organization of Differing Types of Memory
- Presence Identification of Memory

3. Security Considerations

- Manageable, Affordable, Non-intrusive Access
- Memory Read/Write Locking
- Decommissioning of Tags



Areas of Central Focus: continued

4. Dense Reader Environment Considerations

- Defined typical # of readers, environment, product mix and speeds of reads
- Scenarios:
 - Dock Doors
 - Racking in DC
 - Shelf in Retail Store
 - Customer Checkout
- Mobile readers entering field of stationary readers



Demonstration Scenarios - Read

#	Scenario	Scenario Category	Tagging Level	# of Tags	Interrogation Region (m ³)	Tag Antenna size (mm)	Maximum Read Range (m ³)	Max Tag velocity (m/s) or time stationary (s)	Required Read Reliability	Notes (type of material)
1	Hanging garments on a metal mobile hanger rack	C, F	0	50	1.5m x 1.5m x 2.0m	Specific to size of brand tag	1.5 m	3 m/s	99.99	Plastic hanger, cloth
7	Dock door portal	J	0	150	1.2m x 1.0m x 2.4m (48" x 40" x 96")	76.2 mm x 76.2 mm (3 in x 3 in) Mixed orientation	3	1.5 m/s	99.98	Printer supply chain scenarios
8	Apparel POS	K	0	25+	Counter size approx 1m x 1m x 0.25m	Product specific	Limited to region	Stationary	99.98	Loose garments heaped for checkout



Demonstration Scenarios - Read

#	Scenario	Scenario Category	Tagging Level	# of Tags	Interrogation Region (m ³)	Tag Antenna size (mm)	Maximum Read Range (m ³)	Max Tag velocity (m/s) or time stationary (s)	Required Read Reliability	Notes (type of material)
11	DVD in adjacent shelf slots	L	0	12 tags per slot	Slot size 0.15m x 0.3m x 0.3m (6" x 12" x 12')	25 mm-OD 12 mm-ID	0.3m; <0.15m	1 s	99.98	Indoor conditions; std DVD pkg; no physical barrier between slots, max. 40 adjacent slots per shelf
15	Vial & Ampoules in case	A	0,1	100	0.2m x 0.2 m x 0.05 m (8" x 8" x 2") Ampoules arranged vertically	9 mm round	0.15 m	0.25 m/s <5 s stationary	3.4 defects / million <i>(this is a goal)</i>	Liquid-filled ampoule w/ antenna in cap
18	Retail Pharma Tote	G	0	150 (random orientation)	0.76 m x 0.45 m x 0.25 m 2.5' x 18" x 10"	Specific to product	1.2 m (4'); <0.076 m (<3")	Stationary, 3-5 s	99.98	Mixed materials (liquids, blister packs, tablets); 85% of items have some foil/metal; totes are plastic



Demonstration Scenarios - Write

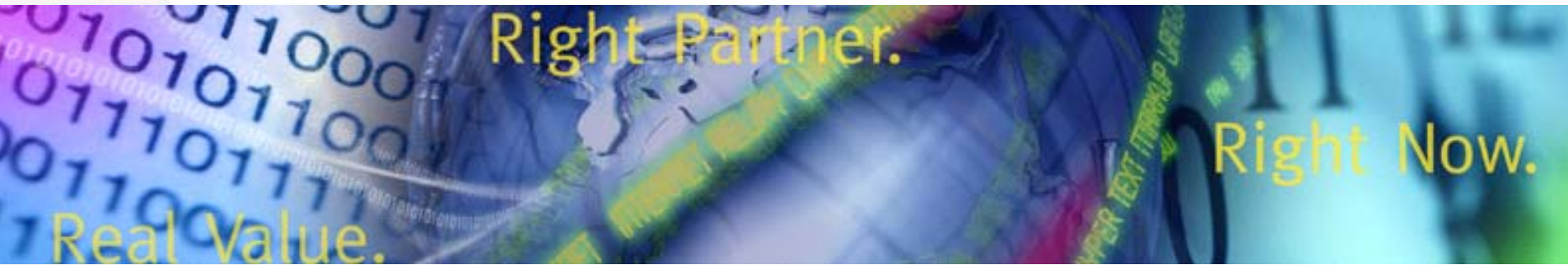
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1	Vial & Ampoule	A	0	1	N / A	9 mm circle ² 5 mm x 12 mm label	1.5 cm	0.1 m/s	3.4 defects / million <i>(this is a goal)</i>	2 mL Vial T303 ² in flip cap



Next Steps

- Jan 18 – Proceed to Phase 2; gather requirements from key external stakeholders – FMCG/HLS/DoD
- Jan/Feb – HAG to confirm technology supplier & scenario match-ups to ensure demo completeness
- Feb/Mar – Technology suppliers to build/test solutions
- Mar 22-23 – HAG/ Technology suppliers demonstration
- April / May – HAG Face-To-Face

Outcome of March demo should determine timeline for HAG to provide technology recommendation



HLS BAG

Pedigree Joint Requirements Group Update

Ted Ng

Director, Emerging Technology

McKesson Corporation

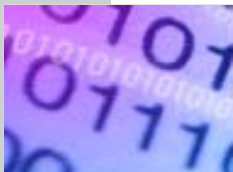
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FDA Anti-Counterfeiting Report February 18, 2004

“RFID tagging of products by manufacturers, wholesalers, and retailers appears to be the most promising approach to reliable product tracking and tracing”

Supply Chain Threat! Counterfeit Product



Label font for product name and concentration is narrower

Label font for product name and concentration is rounder

AMGEN COUNTERFEIT



Font used for LOT number and EXP on carton is rounder

Font used for LOT number and EXP on carton is narrower

COUNTERFEIT



Crisp, high-quality print on box

Poor print quality on box

COUNTERFEIT



Crisp, high-quality print on label

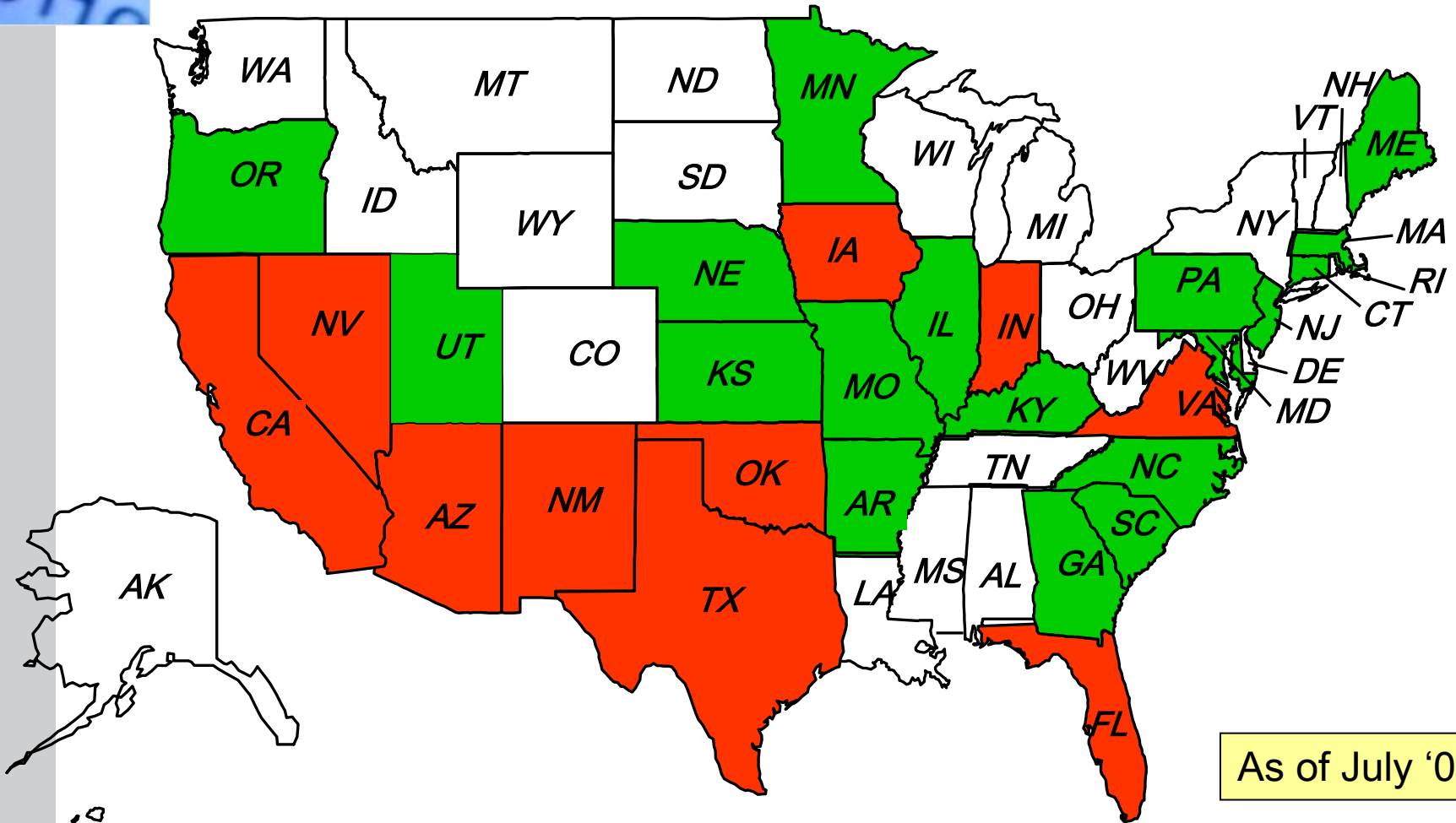
Poor print quality on label

AMGEN COUNTERFEIT

Photo: <http://www.fda.gov/oc/initiatives/counterfeit/photo2.html>

MIT RFID Academic Convocation - 1/23-24/2006

2005 State Licensure/Pedigree Legislation



As of July '05



Passed



Proposed





The Solution is... “Identification and Tracking”

How?

- High Risk Items
- High Demand
- Counterfeited
- Controlled/DEA Rx
- Top xx Drugs
- Life Style Rx

What is a Rational Adoption Approach?



Florida Pedigree

Pedigree papers require histories identifying previous sales and product information that date back to the drug manufacturer.

Information needed:

- Prescription Name
- Manufacturer/Distributor Name
- Dosage Form
- Prescription Strength
- Container Size
- Lot Number Quantity
- Prescription Owner's Name/Address
- Prescription Shipment Location Name/Address
- Transaction Dates

**Pedigree starts with Wholesaler/Distributor
- Required on All drugs on July 1, 2006**



Uniform Data Elements

- Drug Name
- Amount (container size & quantity)
- Dosage form
- Strength
- Lot number/Expiration dates
- Manufacturer/Repackager Name
- NDC ???????
- Unique Tracking Number
- Shipping Date
- Receipt Date
- Name
- Address (street, city, state, zip code)
- Telephone Number
- E-mail address (if available)
- State License Number
- Certifying Name
- Certifying Address (street, city, state, zip code)
- Certification of document
- Reference Number (Invoice, PO)



Missing Pedigree System

- Where does it start?
- Who is responsible?
- Who will enforce?
- What is “Authentic” Product?
- Who keeps what data?
- Who pays for this system?
- What data is the required?
- What if “business cost” to high for selected participants?
- I know we need standards!!!!



Information Systems Deliverables

Guidelines:

- Information Management Architecture
- Logical Data Model
- Information Flow Diagram
- EPC Network Architecture

Rules for:

- Data Synchronization
- Data Validation
- Data Access
- Data Ownership
- Data Sharing
- Data Retention
- Data Security
- Data Storage/Locality



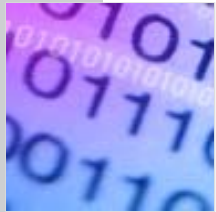
RFID Hardware - Software

- **Hardware - Read/Write**
 - Most existing “mandates” specify G2
 - G2 Tags now in prototype – scaling for volume
 - Hardware becoming available – singles, HF+UHF
- **Software - “evolving”**
 - Edge software expanding
 - Middleware software expanding
 - EPCglobal Network Architecture –
 - Data Public vs. Enterprise
 - Pedigree vendors – “niche”
- **Integration of Hardware and Software**
 - Network based appliances
 - Workflow based – Intelligent devices



Summary of Issues

- Privacy and Security
- Data Network (Central vs. Distributed)
- Data Ownership vs. Data Sharing
- Product Identification schema (Local vs. Global)
- Item Level Tagging – performance
 - Different material types...
- Forward & Reverse Supply Chain participation
- State and FDA - Epedigree model
- Uniform implementation Standards



Summary of Issues

- Tag Frequency Standard
- Technology maturity – evolution/\$\$\$
- Conflicting Industry Group Requirements
- Adoption Approaches
- Need XX% of supply chain to adopt
 - Caution: intermediate technologies



Focus on Business Areas

RFID Scenarios

**Safe & Secure
Supply Chain**



- Regulatory Compliance
- Product Security
- Consumer Safety
- Theft / Shrink Management

**Streamlined
Reverse Logistics**



- Expiration Dating Management
- Lot & Batch Tracking
- Returns Management
- Recall Expediting

**Accurate
Operational
Efficiencies**



- Shipping Accuracy
- Receiving Accuracy
- Operational Productivity

Educate, Educate, Educate!!!