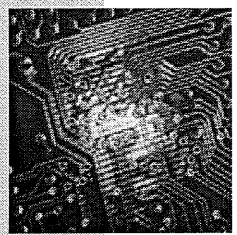
# California Board of Pharmacy

## State of Pedigree and EPC/RFID Standards

Mike Rose – Johnson and Johnson

Ron Bone – McKesson Pharmaceutical Supply



# EPCglobal Community

| | |
|---|---|
| **Established** | **Nov-2003** |
| **Mandate** | - Develop user-driven technical standards for EPC<br>- Support adoption and implementation of EPC<br>- Leverage 30+ year expertise in managing globally unique numbers (UPC and barcode) |
| **Principles** | - Not for profit standards organization<br>- User driven and governed (all supply chain roles)<br>- Public policy and regulatory support<br>- Direct, practical support for industry initiatives<br>- Key value driver is standardized data exchange<br>- Global implementation support (103 offices)<br>- Committed to working with government, industry associations, other standards bodies<br>- Support large, medium and small companies |
| **Standards Work** | **1,600+ global participants** |
| **Subscribers** | **800+ global subscribers** |

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# EPCglobal Community

| | Global Membership | | | |
|---|---|---|---|---|
| | Jun-04 | Dec-05 | Current % | % Increase |
| Asia | 21 | 158 | 19.6% | 752.4% |
| North America | 132 | 498 | 61.9% | 377.3% |
| Europe | 36 | 124 | 15.4% | 344.4% |
| Middle East and Africa | 2 | 8 | 1.0% | 400.0% |
| Latin America | 0 | 17 | 2.1% | n/a |
| | 191 | 805 | | 421.5% |

- 30 of top 40 global **pharmaceutical manufacturers**, 16 of top 20 US manufacturers
- 3 of top 4 **retail pharmacies** and 4 of top 6 **supermarket pharmacies** are part of EPCglobal (20,000 locations in total)
- 4 of top 5 **medical devices** companies are current subscribers

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# EPC in the Healthcare Industry

- EPCglobal Healthcare Action Group formed in 2004
  - **US members represent 38 of 40 largest manufacturers**
  - **3 largest distributors**
  - **Major retailers**
  - **Formed in association with HDMA, NACDS and others**
- Active participation in all key supply chain roles
  - **Manufacturers, Distributors, Retailers, Hospitals**
- Focused on addressing critical needs:
  - **Pedigree Management (including a Pedigree Messaging Standard)**
  - **Air Interface Standard for item level tagging**
  - **Serialization (the format of the EPC on the tag)**
  - **Decommissioning of tags**
  - **Network Security**
- EPCglobal helped form and supports the Unified Pedigree Coalition

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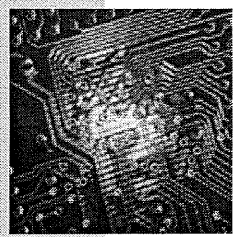

# Safe and Secure Supply Chain

## *EPC/RFID*

- Read and authenticate shipments with no "line of sight" needed
  - **Confirming inbound receipts of item level product**
  - **Identifying expired items w/o handling each item**
  - **Receipt of pallets and cases with out disassembly**
  - **Reduced physical handling = reduced risk/increased security**
- EPC takes advantage of best practices for data sharing
  - **Distributed data (data is held by owner)**
  - **Lower cost to supply chain**
- Industry actively moving towards standardization
  - **Item Level Requirements identified**
  - **EPCglobal Technology Demonstration March 23-24**
  - **Development of new/modified standard**

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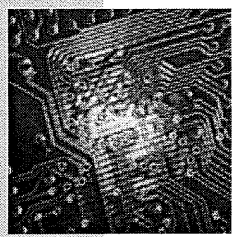

# Safe and Secure Supply Chain

## *EPC and Public/Private Leadership*

- Current EPC implementations by global leaders indicate long-term commitment
- RFID has the capability to solve critical regulatory issues
- Physics and standards challenges are being addressed
  - **Not all products are RFID candidates at this time – Biologics, proteins, metal & glass**
- Tag and reader prices are coming down
- Pilots are underway and learnings are contributing to standards efforts

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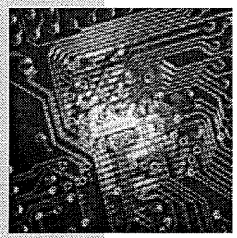

# ePedigree and RFID Challenges

*Industry Challenges:*

- **Data Sharing Issues**
- **Non-serialized Items**
- **Patient Privacy**
- **Public Policy**
- **Regulatory Considerations**
- **Cost/Benefits Differ by Stakeholder**
- **End-to-End Supply Chain Implementation Essential for Mass Adoption**
- **Lack of Universal Pedigree Agreement**

*Technology Challenges:*

- **Serialization**
- **Tag Frequency**
- **Performance**
- **Package Size**
- **Physical Characteristics**
- **Event Vocabulary**

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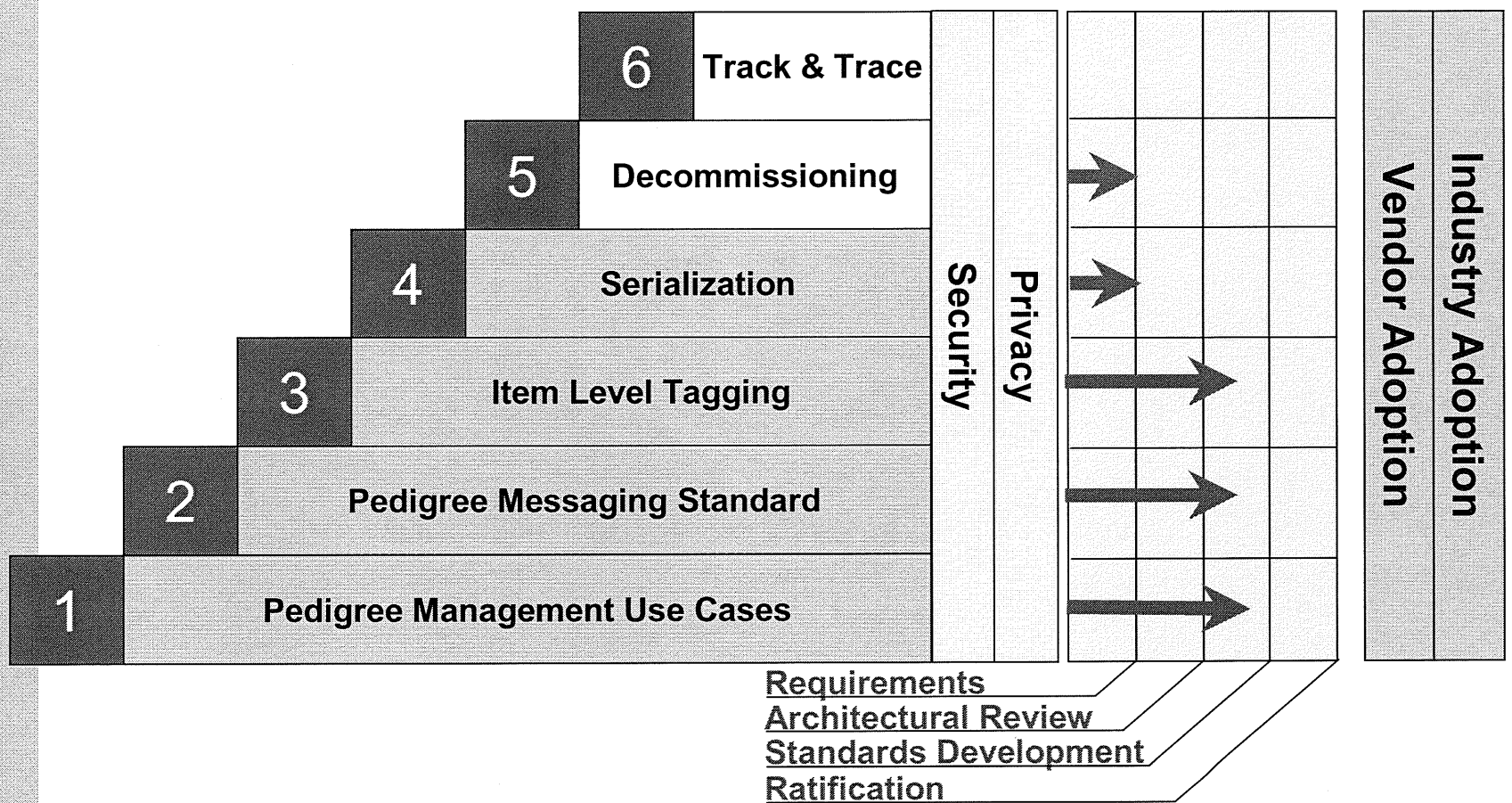
# E-Pedigree Standards

## State of the Standards

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# E-Pedigree Standards

## Key Objectives and Process Requirements

**Objectives:**

- Provides **universal interchange format** to express pedigree requirements of varied state regulations as drug products flow from one state to another
- Enable trading partners to send and receive pedigrees in a **secure and interoperable** manner that leverages existing B2B technologies and processes

**Process Requirements:**

- Each party engaged in the wholesale distribution of prescription drugs must **provide a pedigree** to the recipient for sales, returns, and transfers of prescription drugs
- Pedigrees must contain a **certification** (via signature) by the sender that the information is true and accurate
- Pedigrees must be **authenticated** by the recipient prior to receipt of drugs
- Recipient must add **receipt and authentication signature** to pedigree
- A pedigree received by or provided by an organization is a **subject to recordkeeping requirements** for record retention and record availability

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# E-Pedigree Standards

## E-Pedigree Interchange Requirements

- Common format that meets PDMA and state needs
  - **Supports all required data elements for PDMA and states**
  - **Extensible format supports future state requirements**
- Supports regulatory and business requirements
  - **Serialized items (Could potentially support Non-serialized items with additional study)**
  - **Repackaged products**
  - **Sales, transfer, and return transactions**
  - **Creating electronic pedigree from paper pedigree**
  - **Digital signatures and electronic authentication**
- Enables interoperability among trading partners
  - **Representation of pedigrees in a common portable format**
  - **Exchange using existing business data transfer mechanisms**
- Supports Standard Security Protocols
  - **Public Key Infrastructure (PKI)**

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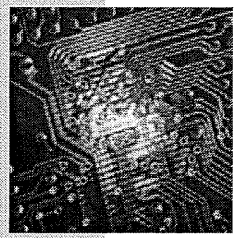

# Next Steps

## Beyond Standards Ratification

- Capital Planning
- Process Reengineering
- Systems Integration
- Infrastructure Build-Out
- Scale-Up

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# E-Pedigree Standards

## Pedigree Data Elements

- **Product Information**
  - Drug name
  - Manufacturer
  - Product NDC, dosage form, strength, container size
- **Item Information**
  - Lot number and expiration date
  - Quantity of units by lot
  - Product serial number (if serialized)
- **Transaction Information**
  - Transaction identifier (e.g., PO, Invoice) and date
  - Transaction type (e.g., sale, transfer, return)
  - Date received
- **Trading Partner Information**
  - Business name, address, and license of seller
  - Alternate ship-from location of seller
  - Seller contact information for authentication
  - Business name, address, and license of recipient
  - Alternate ship-to location of recipient
- **Signatures/certifications**
  - Digital signature of seller
  - Digital signature of recipient

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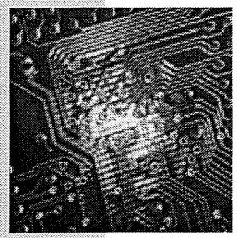

# Thank You!!

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