EPCglobal
Healthcare & LifeSciences Business Action Group
State of Pedigree and EPC/RFID Standards

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AGENDA

- Background -- EPC in the Healthcare Industry
- Organizational Alignment
- HLS Progress and Capabilities
- EPCglobal Medical Devices Summit
- Summary of Critical Issues

EPCglobal Community

Established	**Nov-2003**
Mandate	**- Develop user-driven technical standards for EPC - Support adoption and implementation of EPC - Leverage 30+ year expertise in managing globally unique numbers (UPC and barcode)**
Principles	**- Not for profit standards organization - User driven and governed (all supply chain roles) - Public policy and regulatory support - Direct, practical support for industry initiatives - Key value driver is standardized data exchange - Global implementation support (103 offices) - Committed to working with government, industry associations, other standards bodies - 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**
  - **FDA involvement**
- Active participation in all key supply chain roles
  - **Manufacturers, Distributors, Retailers, Hospitals**
  - **Medical Devices RFID Summit – March 2, 2006**
- 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

Initial Key Industry Drivers for HLS

Why would we spend our time doing this?!?!

- Patient Safety
- FDA
- State pedigree

However, these are only initial focal points….

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**
  - **Serialization formats proposed**

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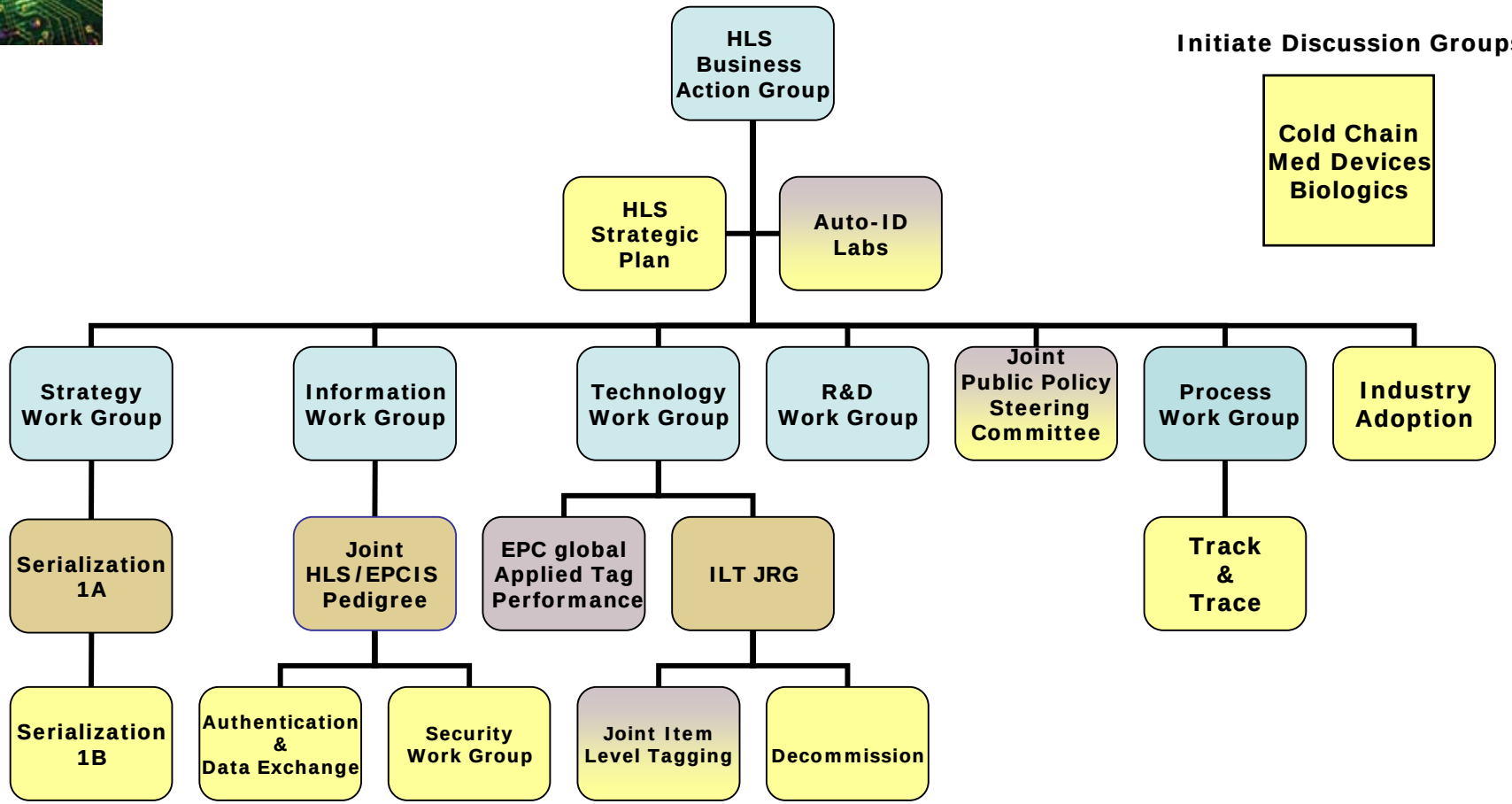
Safe and Secure Supply Chain

EPC and Public/Private Leadership

- Current EPC implementations by global leaders indicate long-term commitment
- RFID/EPC 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

HLS Work Group & Task Force Alignment



- HLS Top Priorities – 2006
- On-Going HLS WGs
- On-Going EPC WGs
- HLS Top Activities – 4Q05

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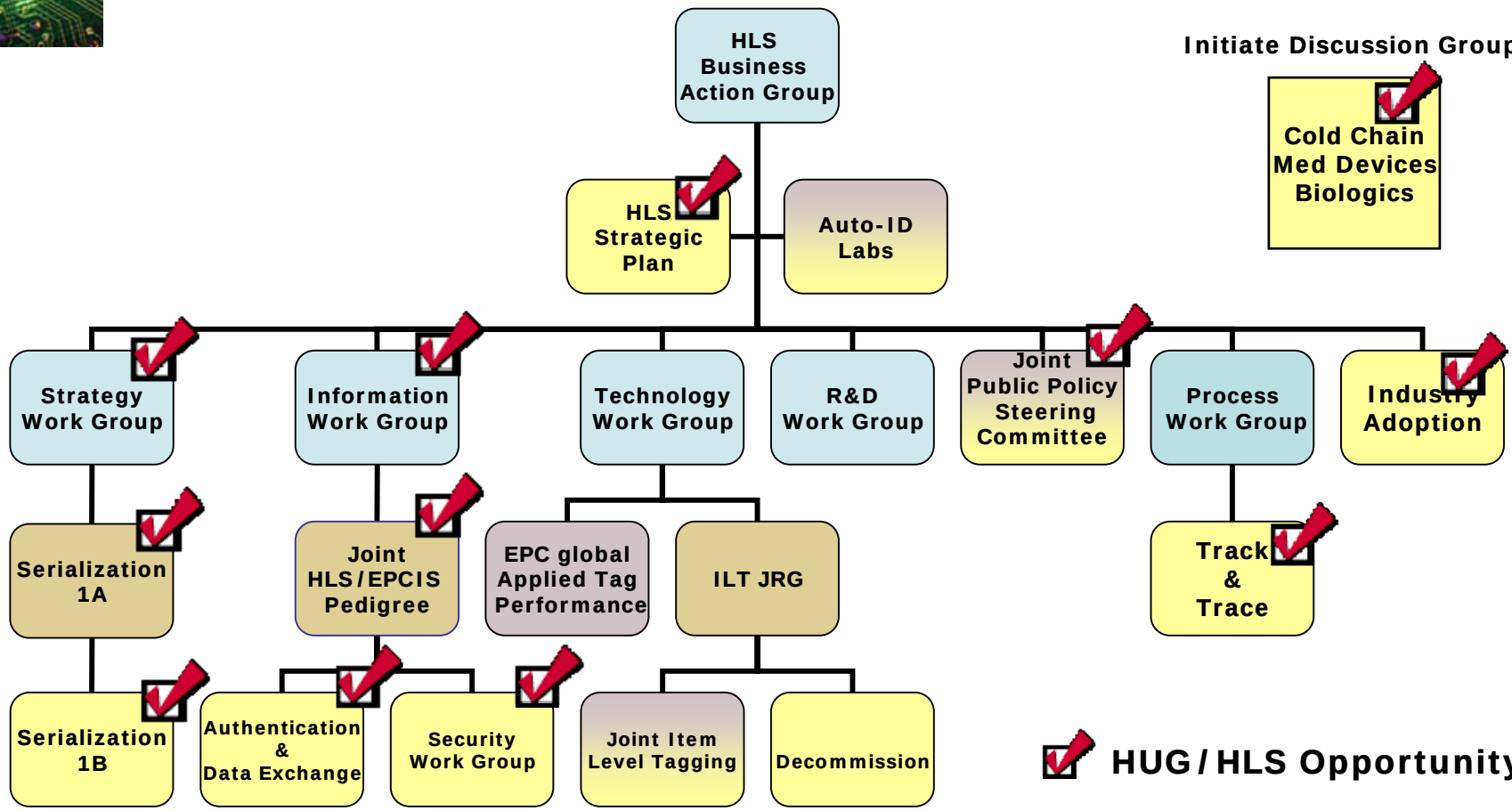
HUG/HLS Areas for Collaboration



HLS Top Priorities – 2006

On-Going HLS WGs

On-Going EPC WGs

HLS Top Activities – 4Q05

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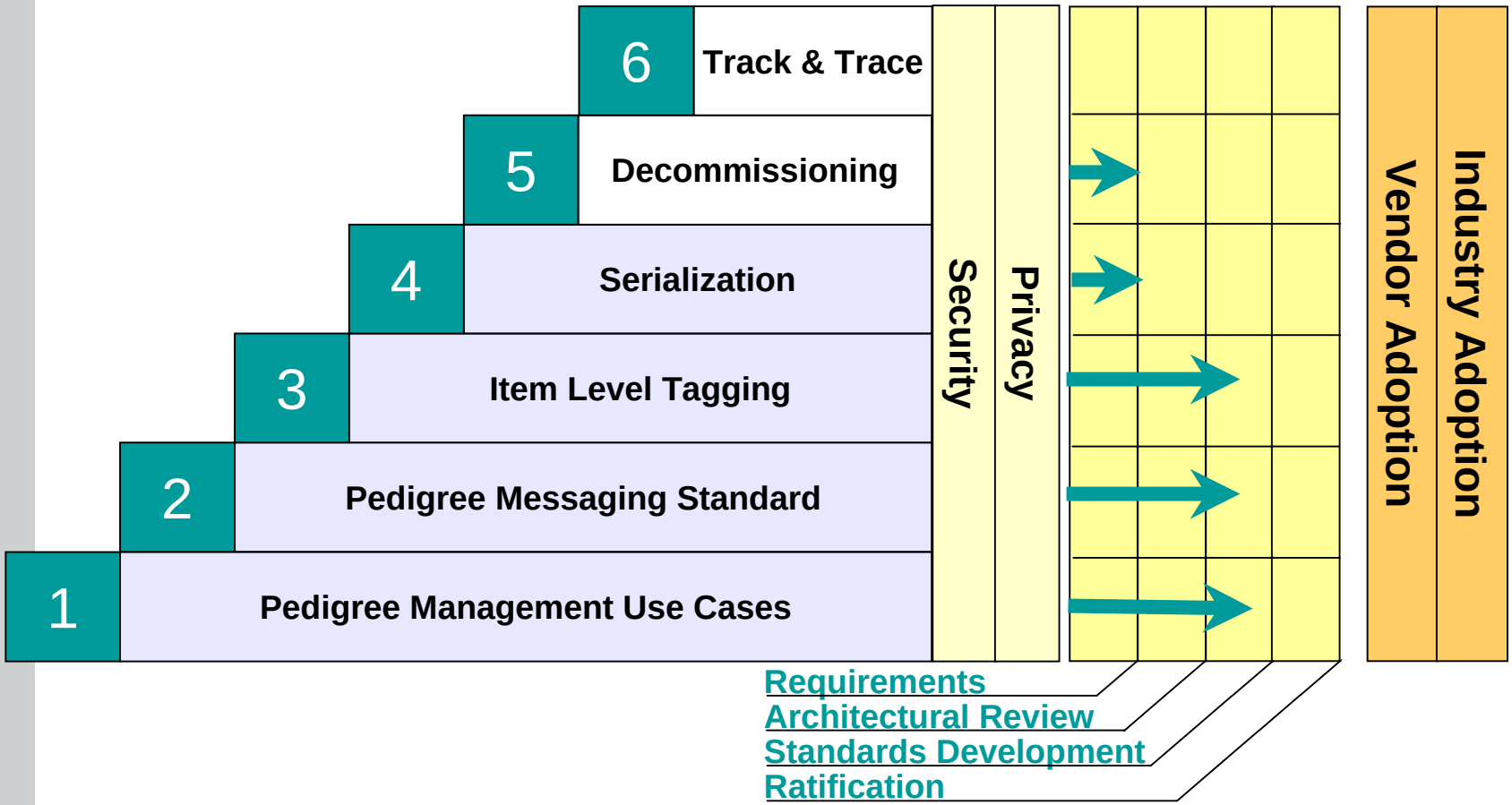
Overview to HLS Progress and Capabilities

- Item Level Tagging
- ePedigree
- Serialization
- 2006 Focus Areas

HLS Areas for Standards

State of the Standards



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Item Level Tagging Joint Requirements Group Progress – 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**
  - **Vial & Ampoule Write**
  - **Retail Pharma Mixed Tote**
- Jan 18 – Proceed to Phase 2; gathered requirements from key external stakeholders – FMCG/HLS/DoD
- Jan/Feb – HAG confirmed technology supplier & scenario match-ups to ensure demo completeness

ILTJRG - Next Steps

- Feb/Mar – Technology suppliers to build/test solutions
- Mar 23-24 – HAG/ Technology suppliers demonstration
- April / May – HAG/SAG/ILTJRG Face-To-Face

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

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

E-Pedigree Standards

E-Pedigree Interchange Requirements

- Common format that meets FDA's 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 – not RFID dependent)**
  - **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)**

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**

Serialization

- Two options developed
  - sGTIN - NDC code with random serial number
  - Company identifier with random serial number
- Concerns have been raised about each option
  - Privacy
  - Efficiency and effectiveness at every read point
- Next Steps
  - Review feedback from market research on privacy and RFID
  - Obtain input from DEA and FDA
  - Ensure standard is carrier independent
  - Leverage full GS1/EPCglobal capabilities

2006 Focus Areas - Capabilities

- Track & Trace
  - Intended to utilize EPC to track material where pedigree is not going to be required
- Reverse Logistics
  - Return of product initiated by Manufacturer, Wholesaler, Retailer or Hospital. The overall intent is to design processes and standards regarding the “reverse” flow of healthcare product across the Supply Chain.
- Authentication
  - Intended to utilize EPC to authenticate individual product, information and identification
- Patient Care Management (Future)
  - Intended to utilize EPC to increase the effectiveness of patient care management.

Medical Devices Summit

- HLS original intent is to cover medical devices and pharmaceuticals
- Medical Devices RFID Summit – March 2, 2006
  - Collaboration between EPCglobal and Medical Devices Supply Chain Council
- Agreed to draft charter for EPCglobal HLS Medical Devices workgroup

Johnson & Johnson

BD

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stryker

zimmer

Alcon

WelchAllyn

Nobel Biocare

Edwards Lifesciences

Boston Scientific

Kimberly-Clark

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Summary of Critical Issues

- Policy
  - Privacy and Security
  - State and FDA – ePedigree model
  - Adoption Approaches – Getting to a “Tipping Point”
  - Data Network (Central vs. Distributed)
  - Data Ownership vs. Data Sharing
- Technology
  - Tag Frequency Standard
  - Serialization Standard – carrier independent
  - Item Level Tagging – performance, materials, volume…
  - Technology maturity – evolution/$$$
- Industry Adoption
  - Uniform Implementation Standards
  - Conflicting Industry Group Requirements

Next Steps – Managing Expectations

Beyond Standards Ratification

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

Thank You!!

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