Global Healthcare User Group

Automatic Product Identification
in Support of Wholesale Distribution

December 2005

Ronald Bone
SVP, Distribution Support
McKesson Supply Solutions
Agenda

- Who is McKesson
- Current use of Scanning
- Serialization and RFID
- Florida Pedigree
- HLS Priorities
McKesson facts

- Founded 1833, headquartered in San Francisco
- 24,000 employees
- $80.5 billion in revenues
- $11.7 billion market cap

**REVENUES**
- Pharma Solutions: $76.3 B
- Medical-Surgical: $2.9 B
- Provider Technologies: $1.3 B

**OPERATING PROFIT**
- Pharma Solutions: $1 B
- Medical-Surgical: $102 M
- Provider Technologies: $107 M
Delivering Value from the Center of Healthcare

Pharmaceutical & medical-surgical distribution to all sites

Solutions for medication safety

Inpatient automation

Drug cards for seniors

Pharmaceutical repackaging

Specialty pharmaceuticals

Information systems for hospitals, payors, home care, and physicians

Retail pharmacy automation

Disease management

McKesson
Empowering Healthcare
McKesson Has Historically Employed Technology

- **Econo Most Electronic Ordering** 1969
- **Econo Link Electronic Ordering** 1989
- **Electronic Data Interchange** 1992
- **Supply Management Online Web Technology** 2000
- **Closed Loop Delivery Technology** 2001
- **RFID Shipment Pilot** 2003
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Acumax – Barcode Reader

- **Everything is bar coded and scanned**
  - Product
  - Shelf & case storage locations
  - Moveable units (totes, pallets, etc.)
  - Drop zones

- **Every process is confirmed by scanning**
  - Receipt
  - Putaway
  - Replenishment
  - Picking
  - Cycle counting
  - Staging on the shipping dock

- **No paper is used in the warehouse**
Stats on scan reads

- 2,700 wearable units deployed in the system
- One facility performs ~ 1 million scans per day
- The balance of the network scans ~ 3 million scans per day

- All four data points are not always there or readable
  - NDC
  - Qty per case
  - Lot
  - Expiration date.

- Poor label quality (must be able to scan for pedigree)
- Currently many case labels cannot be read
- Issues especially around distinguishing different strengths
Agenda

- Who is McKesson
- Current use of Scanning
- Why Serialization and RFID
- Florida Pedigree
- Issues Moving Forward
There are various expectations within the industry regarding implementation of RFID

<table>
<thead>
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<th>2004</th>
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<th>2006</th>
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<td>FDA Adoption Guidelines</td>
<td>Feasibility studies for the tagging of pallets, cases, &amp; packages</td>
<td>Tagging of <em>some</em> pallets, cases, &amp; packages for <em>highly counterfeit</em></td>
<td>Tagging of <em>most</em> pallets, cases, &amp; packages for <em>highly counterfeit</em></td>
<td>Tagging of <em>all</em> pallets &amp; cases</td>
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<td></td>
<td>Tagging of <em>some</em> pallets &amp; cases for others</td>
<td>Tagging of <em>most</em> packages at unit level</td>
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<td>Pharma Industry Org Guidelines</td>
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<td>NACDS: tagging at the pallet &amp; case level</td>
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<td>Other Industry Requirements</td>
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</table>

**HDMA**: tagging at the pallet & case level

**FDA Adoption Guidelines**: Feasibility studies for the tagging of pallets, cases, & packages

**Pharma Industry Org Guidelines**: NACDS: tagging at the pallet & case level

**Other Industry Requirements**: Tagging of all pallets & cases

**WM C2**: Tagging at the unit level

**HDMA**: Tagging at the unit level
FDA Combating Counterfeit Drugs

February 2004
Combating Counterfeit Drugs

December 2004
Called for pedigree Database

May 2005
Combating Counterfeit Drugs: A Report of the Food and Drug Administration Annual Update
FDA Opened Cases ’97 to ‘04

Counterfeit Drug Cases Opened by FDA per Year

Source: FDA Annual report
## Where Drug Incidents Occur

<table>
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<tr>
<th>Location</th>
<th>Fake</th>
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<td>UK</td>
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</table>

Source: USA Today – Summer 2005
Recent Negative Press Coverage

Dangerous Doses
How Counterfeiters Are Contaminating America's Drug Supply
Katherine Eban

Vanity Fair May ‘05

DRUGSTORE COWBOYS
THE DANGEROUS TRAFFIC IN FAKE PRESCRIPTION MEDICINES
Counterfeit Labeling Of Epogen

Source FDA website
Pedigree Legislation Active in 28 States
As of August 24th, 2005

- **Passed Legislation and Immediate Action Needed**
- **Passed Pedigree Legislation**
- **Pedigree Legislation Introduced**
- **No Pedigree Legislation**

As early as Jan. 1, 2007
No rules defined

July 1, 2006
No rules defined
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Florida Regulatory Update

Open issues with the Department of Health – Next Meeting January 19

- Pedigree Auto-Authentication Proposal
  - Documents cannot technically be embedded and authenticated
  - Issues will occur because some will be XML and others EDI
  - Recommend that Affiliated Group be allowed as referred to in the current Specified Drug list language

- Drop Shipments - Products shipped directly from the manufacturer to the retailer should be exempt

- Emergency Shipments - If a facility should be rendered unusable - Allow for exemption for products purchased from a non-pedigree facility

- Serialization - Needs to be a widely used standard with agreed upon technology

- Current Inventory - It may take 3 to 6 months to get the product out of the inventory after July 2006. Need to treat slow moving product differently and have a phasing in of all products
Key Florida Dates

- January 19th Rule Session
- January/February ’06 - Final Rule expected
- March ’06 – Electronic Purchase Order Confirmation and Advance Ship Notices from Suppliers
- March ’06 – All products received in the warehouse with pedigree
- July ’06 – Florida Pedigree Law in place
Issues to Consider

- Technology must continue to evolve for broad industry adoption - Critical Issues for serialization are:
  - RFID hardware interaction with other devices
  - Hardware compatibility and tag frequencies
  - Proper network security and access

- **What role do 2D Barcodes have**

- Implementation for broad adoption may be more complex than anticipated.
  - Requirements for systems and packaging—especially in addressing data sharing and consumer privacy concerns.

- Pharmaceutical *Industry* must continue to actively engage with Federal/state regulatory agencies, standards-setting organizations, and industry trade associations.
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HLS Work Group & Task Forces - 2006

HLS Business Action Group

HLS Strategic Plan

Initiate Discussion Groups

Cold Chain Med Devices Biologics

On-Going HLS Working Groups

Strategy Work Group
- Serialization 1B
- Joint HLS/EPCIS Pedigree R1

Information Work Group
- EPC global Applied Tag Performance

Technology Work Group
- Joint Item Level Tagging FMCG, DoD & HAG

R&D Work Group
- Decommission

Joint Public Policy Steering Committee

Process Work Group
- Track & Trace

Implement & Adoption

Security Work Group
- Tag Frequency

Auto-ID Labs

Track & Trace

Reverse Logistics

HLS Top Priorities – 2006

On-Going EPC Working Groups

Next few months (2005/Early 2006)

HLS Strategic Plan

Strategy Work Group

Information Work Group

Technology Work Group

R&D Work Group

Joint Public Policy Steering Committee

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Next few months (2005/Early 2006)