SMART Consulting, LLC

- In Business since 2006
- Excellent Reputation
- Experienced doing RFID Cases
- Worked with Wal-Mart and Target
- Involved with Organizations: EPCglobal and ISO
- Hired by the Pharmaceutical Care Management Association

Team: Mark, Vincent, Alena
“FRAUD IN A BOTTLE”
This is a National Problem.
(The Wall Street Journal, January 24, 2006)
Who are the Stakeholders?

- Manufacturers
- Hospitals
- Distributors
- Retailers
- Large Pharmacy Chains
- On-line drug retailers
- End-Users
Step 2 Determine the scope and assumptions

- 54% of Prescription Drugs go to wholesalers

Scope: to implement a system using RFID to reduce the number of fake drugs dispensed in U.S.

Open-loop system, track at the manufacturing and retailing levels.

Assumptions:

- Able to integrate with existing medicine-control programs
- Manufacturer must do tagging and provide data online:
  - A. Pallet & Case levels using UHF.
  - B. Item level – HF (maybe UHF soon)
- Retailers, hospitals & distributors are validating directly to the manufacturers
Step 4: Biz Processes & Interfaces

- **Current Business Processes:** Manufacturing, Distribution, Retail, End-User.
  - In-scope: manufacturing and retail.
- **Physical Infrastructure**
  - Manufacturing: Readers & Antennas, RFID printer(s), RFID tags, Middleware.
  - Retail: Readers and Middleware
- **IT infrastructure**
Processes & Interfaces

- **First Stage**
- Our plan will initially start with tagging individual units with HF chips, with unique serial numbers, and the specific factory where the batch was manufactured. This will be a fairly simple slap and ship operation.
- The system initially is designed to be a open loop system, however it will only be tracked at the manufacture and then verified at the final retail location.
Second Stage

- In addition to tagging individual units with HF tags, cartons and pallets can eventually be tagged with UHF for supply chain tracking.
- The existence of RFID hardware for both HF and UHF at the manufacture enables them to use it for tracking raw materials and inventory within the plant.
- Retail chains could potentially use the system to detect expired lots of medication.
- Amount of drugs sold to the retailer could be matched with insurance billing to ensure no substitutes, or dilutions are happening at the pharmacy level.
Step 5: Complimentary or Competing Business Initiatives

- FDA & Homeland Security
- EPC Global
- ISO
- Manufacturers
- Gen2
- DoD
- Wal-Mart RFID Mandates
- Sears
- Walgreens

• Consumers Against Supermarket Privacy Invasion
• Some Wholesalers
Step 6 Strategic and Economic Benefits

- RFID will enable better drug pedigree tracking by verifying a drug's lineage, each bottle with a unique serial number.
- Accurate tracking of medication tracking will lower the $40 billion a year to black market drugs, fake medication, and lawsuits resulting from consumers ingesting fake medication.
Step 6 Strategic and Economic Benefits (continued)

- Retailers will inbound medication and though the use of hand held or fixed location RFID scanners when in bounding medication into inventory.
- Serial numbers are sent to the manufacture via Internet to be checked for authenticity, content and marked in the manufacture database as having reached its final destination at drugstore XYZ #123.
- Serials that fail to pull up or pull up as previously reaching a retail location will be pulled. In addition the store which has the other duplicate number will be notified and their batch pulled as well.
Investment Requirements

- Manufactures will be setup for a simple slap and ship system.
- Initially each factory will be outfitted with conveyors, tag applicators, and conveyor mounted scanners.
- Middleware will be needed to inseminate RFID data into corporate database for retailers to access later.
- IT infrastructure may need minor upgrading to handle additional data.
## Investment Costs

### Manufacturer

<table>
<thead>
<tr>
<th>Item</th>
<th>Year 1</th>
<th>Year 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tag Applicator</td>
<td>$60,000</td>
<td>-</td>
</tr>
<tr>
<td>Fix Location Readers</td>
<td>$10,000</td>
<td>-</td>
</tr>
<tr>
<td>Conveyors</td>
<td>$ 6,000</td>
<td>-</td>
</tr>
<tr>
<td>Printronix Printer</td>
<td>$15,000</td>
<td>-</td>
</tr>
<tr>
<td>Software (Middleware)</td>
<td>$200,000</td>
<td>-</td>
</tr>
<tr>
<td>Training</td>
<td>$30,000</td>
<td>-</td>
</tr>
<tr>
<td>Tags</td>
<td>$50,000</td>
<td>$45,000</td>
</tr>
<tr>
<td>Software Maintenance</td>
<td>$30,000</td>
<td>$30,000</td>
</tr>
<tr>
<td>System Maintenance</td>
<td>$10,000</td>
<td>$10,000</td>
</tr>
<tr>
<td>Data Maintenance</td>
<td>$ 6,000</td>
<td>$6,000</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td><strong>$402,000</strong></td>
<td><strong>$91,000</strong></td>
</tr>
</tbody>
</table>
## Investment Costs

### PCMA

<table>
<thead>
<tr>
<th>Manufacture</th>
<th>Year 1</th>
<th>Year 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Client Software</td>
<td>$375,000</td>
<td>56,250</td>
</tr>
<tr>
<td>System Integration</td>
<td>$97,500</td>
<td>-</td>
</tr>
<tr>
<td>Totals</td>
<td>$472,500</td>
<td>$56,250</td>
</tr>
</tbody>
</table>
Investment Costs
Retailer

<table>
<thead>
<tr>
<th></th>
<th>Year 1</th>
<th>Year 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handheld Reader</td>
<td>$1,000</td>
<td>-</td>
</tr>
<tr>
<td>Software</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Software Maintenance</td>
<td>$150</td>
<td>$150</td>
</tr>
<tr>
<td>Data Maintenance</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Training /Setup</td>
<td>$500</td>
<td>-</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td><strong>$1,650</strong></td>
<td><strong>$150</strong></td>
</tr>
</tbody>
</table>

-Costs on the retail side will be minimal.
Refine the process and conduct team training

- Implementation manager will oversee the pilot and make adjustments as necessary to packaging, tagging and palletization process to maximize tag reads. Implementation manager will also train shipping staff on “do’s and don’ts” of RFID.
- IT personnel will be trained on how to make simple changes to the system and make necessary upgrades to existing computer systems to work with the new scanners.
- At the retail level simple training will need to be done on using the handheld scanner and computer system to verify authenticity of product, and what to do if a tag reads duplicate, unreadable or bogus.
Savings Goal

- Circumventing a loss of 10% would be substantial.
- $40,000,000,000 \times 0.10 = $4,000,000,000$
Why will we succeed? 
(drivers, strategies & enablers)

- Manufacturers lose sales
- Brand name gets damaged
- Government mandates
- Pharmacies get sued for dispensing bad drugs
Pharmacy X Case Study - Epogen

- Low-dose Epogen (2,000 units per milliliter) manufactured
- TO a national wholesaler
- TO a pharmacy in Miami
- TO a Florida middleman
- TO an alleged counterfeiter. He packed 110,000 vials of Epogen in paint cans and took them to a Florida trailer park where another man, working in a hut in his backyard, doctored the labels. (Now labeled high-dose Epogen, 40,000 units per milliliter).
- TO two men who bought the vials in the back room of a Florida strip club called the Playpen South and stored them in a beer cooler.
- TO a middleman. He had a line of customers waiting for meds. Sold more than $2 million worth to a paper wholesaler.
- TO paper wholesale company in Texas, sold pharms out of his home.
- TO a registered pharmacist in Florida with a license to distribute. Her involvement made it look legit again.
- TO an Arizona-based wholesaler.
- TO a Kentucky distribution center. The same national wholesaler where it started.
- TO Pharmacy X in New York.
Implementation Roadmap

- Manufacturers (already tagging meds)
  - Develop access to networks & database
  - Obtain several sample bottles
- Develop the middleware & application code
  - Windows program to be installed at each pharmacy
  - Select a WiFi reader, and a tethered reader
- Create and pilot the “launch package”
  - Tethered reader ($1000)
  - Installation CD & manual (free to members)
  - “RFID SECURED” logo, consumer handouts, etc
- Full Product Rollout
The Business Case

- Has your prescription drug seen more strip clubs than you have?
- FDA mandates are coming: paper or RFID
  - (and paper can still be counterfeited)
- Top Line + Bottom Line benefits
The Business Case

- Costs
  - Smart Consulting development:
    - $472,500 (2100 man-hours @ $225/hour)
  - Pharmacies purchase the Launch Package for $1,650 (no cost, no profit)
    - $1,000 for tethered reader
    - WiFi reader is optional