Reference Section IV-A "Questions Concerning Technology" Option 12

Electronic Track & Trace - An Immediate Solution

Comments to the FDA Counterfeit Drug Task Force (1) 40 113

This paper quickly summarizes how proven advanced data capture systems can be used right now to provide an electronic trace & trace solution to the counterfeit drug problem.



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Executive Summary

While there is no "magic bullet" to resolve the counterfeit drug problem, part of the solution needs to be some kind of electronic pedigree for drugs. RFID Track & Trace is an obvious solution; it is however not immediately available, leaving two options:

- i) Waiting until RFID based systems are ready
- ii) Starting now with a solution that offers a future upgrade path to RFID

Fortunately, an advanced data capture system already exists that is less costly than RFID. It is also one that could easily evolve into an RFID solution when economically and technologically feasible -2D Barcode Scanning.

An excellent model for how this system is used in extremely large-scale electronic track & trace applications can be seen at United Parcel Service (UPS).

UPS, the world's largest package delivery company, has been using electronic track and trace since 1992. By 1993 they were delivering over 11.5 million packages a day to more than one million customers. In the year 2000, online tracking requests reached a record-high of 6.5 million in a single day. The approach they employ is 2D Barcode scanning using Symbol Technologies' equipment.

Symbol Technologies, Inc., is a global leader in secure mobile information systems that integrate application-specific handheld computers with wireless networks for data, voice and barcode data capture. Symbol is also at the forefront of RFID development and is familiar with many of the vendors from the October 15th public meeting having worked with them in the past.

The following pages show how an evolvable barcode based track & trace system, coupled with any number of existing anti-counterfeit technologies, would provide a robust, secure supply chain conduit from manufacturer to consumer.

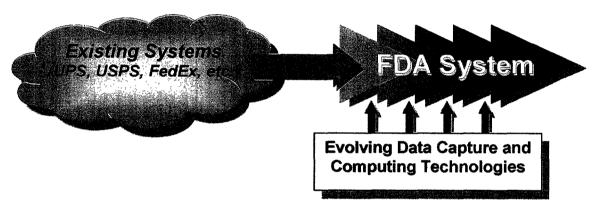


Proposal

Evolution of Existing Models

Existing track & trace systems provide the ability to scan all parcels into and out of any physical location and allow depot supervisors to perform a security check of how many parcels have been loaded onto any given van. In conjunction with web reporting mechanisms, these systems provide information on the whereabouts and tracking history of any given parcel, and measure the performance of drivers with respect to successful deliveries v. failure rate, as well as giving information vital to the general management and performance of the depots.

This paper proposes that this type of system can serve as a foundation for a fast solution to some of the issues faced by the FDA Counterfeit Drug Task Force.

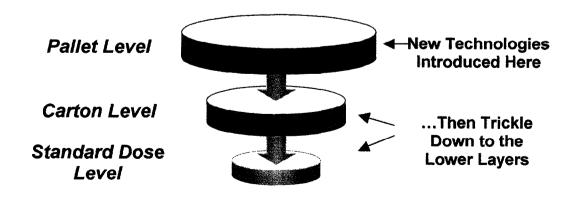


Multi-Layered Model

There are two main advantages of a multi-layered system:

- 1) Less Electronic Transactions
- 2) Gradual Technology Integration

With a multi-layered approach, materials can be tracked at whatever level the packaging has been broken down to. In addition, as new technologies, such as RFID, become more efficient they can be applied to the different packaging levels in a top-down manner.



November 3, 2003.

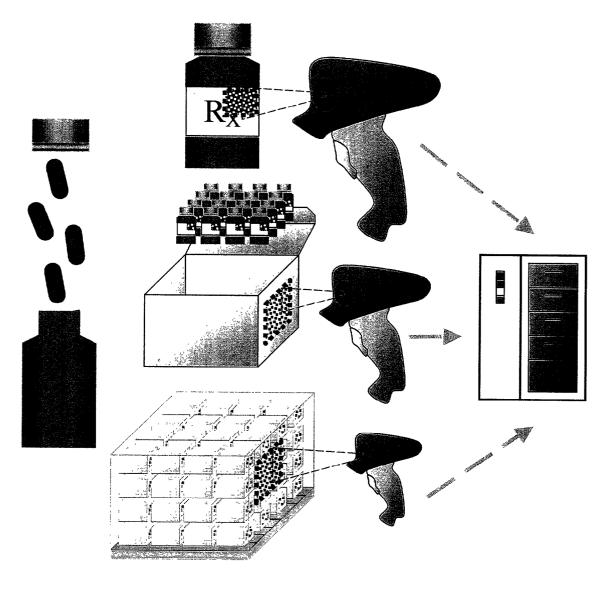
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Existing Technologies

Barcode scanning technologies have been used in electronic track & trace systems for over a decade and have a good fit with the multi-layered approach:

- Dosage packaging receives individual standardized 2D barcode with information on drug type, manufacture site, batch number and dosage number.
- Cartons containing multiple dosages receive individual standardized 2D barcode with information on drug type, manufacture site, batch number and first & last dosage numbers within the carton.
- Shipping (pallet level) packaging receives individual standardized 2D barcode with information on drug type, manufacture site, batch number and first & last carton numbers within the packaging.

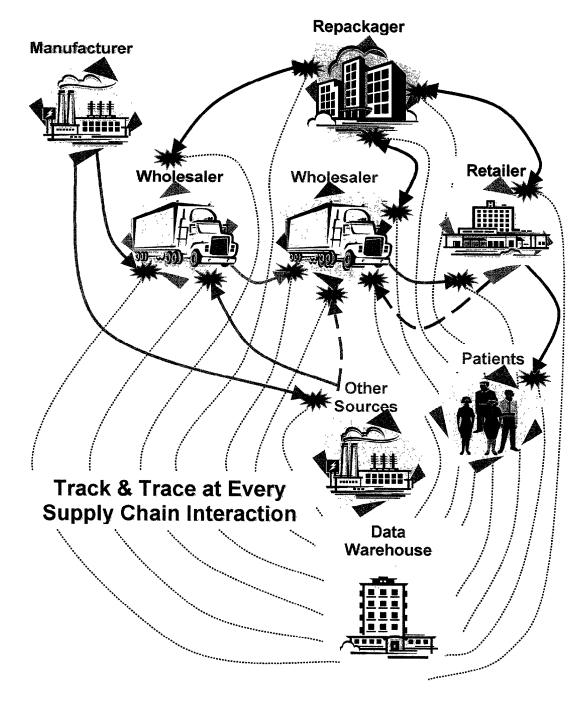




Authentication and Record Revision

At each transfer from one supply chain member to the next the barcode is scanned for two reasons:

- 1) Trace confirm pedigree
- 2) Track enter new "owner" in central database



This is already done in the parcel delivery industry using 2D barcodes. A similar system initially based on this technology can later be integrated with an RFID system when that becomes viable.



Case Studies

These attachments show how products from Symbol Technologies, Inc. have already become the internationally proven choice for large-scale track & trace infrastructures.



Releases by Category:

- · Solutions:
- •Retail General Merchandise
- •Retail Food and Drug
- •Logistics
- Manufacturing
- Healthcare
- Education
- Government
- Hospitality
- Products:
- Bar Code Scanners
- •PDF417 Products (2D)
- Mobile Computing
- Pocket PC
- •PalmOS®
- •Windows® CE
- Wireless LANs
- Consumer Systems
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Symbol Announces U.S. Postal Service Contract with Lockheed Martin Now Worth Approximately \$150 Million

Symbol Hand-held Computers On-Schedule for Use by USPS Mail Carriers

Holtsville, N.Y. -- Nov. 23, 1998 – Symbol Technologies announced today that it received an order for an additional 25,000 mobile computers for



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Service contract with Lockheed Martin Corporation at approximately \$150 million through 1999. The contract, to equip all the nation's mail carriers with mobile computers to track the delivery of Express Mail, Priority Mail, parcels and accountable mail such as certified, C.O.D. and registered, was originally announced as a \$100 million contract.

use by U.S. mail carriers, and that it now values its previously announced U.S. Postal

The U.S. Postal Service has accepted the 200,000th mobile data collection device, which is a computer that is small and light enough (at 12 ounces) for letter carriers to easily carry and use. Symbol is steadily rolling out the remainder of the 300,000-plus unit order to Lockheed Martin, which serves as the prime contractor. It is the largest contract in Symbol's history.

More than 20,000 Post Offices, including major cities and small towns, throughout the U.S., are now using Symbol hand-held computers to scan and collect important delivery confirmation information, including date and delivery time, from the mail. More than 20,000 Post Offices, including major cities and small towns, throughout the U.S., are now using Symbol hand-held computers to scan and collect important delivery confirmation information, including date and delivery time, from the mail. By late February 1999, more than 35,000 Post Offices will be implementing delivery confirmation. The compact, 20-key hand-held computer has been ruggedized to operate in all weather conditions and includes a bright laser diode scan engine that provides greater visibility for reading bar codes in difficult environments. Symbol currently provides data collection solutions to postal services in more than 40 countries and has been a technology supplier to the USPS since 1984.

Beyond the initial order for 300,000 hand-held terminals and nearly 59,000 ethernet cradles, Symbol will provide additional thousands of mobile data collection computers to the USPS, along with additional cradles, spare batteries and professional services.

"The Symbol hand-held computers will enable the Postal Service to meet customers' important needs for information about their shipments," said Julie Rios, USPS Program Manager.

"The use of our hand-held scanning computers by the USPS confirms our leadership position in postal service automation and for providing solutions throughout the entire distribution/logistics pipeline," said Dr. Jerome Swartz, Chairman and Chief Executive Officer, Symbol Technologies.

"Symbol and Lockheed Martin, a world-class integrator, are successfully teaming to provide the USPS a state-of-the-art-solution that will improve every day mail delivery," said Tomo Razmilovic, Symbol's President and Chief Operating Officer. "Symbol is exploring other opportunities for global business with Lockheed Martin."

About Symbol Technologies

Symbol Technologies, Inc. delivers enterprise mobility solutions that enable anywhere, anytime data and voice communication designed to increase productivity, reduce costs and realize competitive advantage. Symbol systems and services integrate rugged mobile computing, advanced data capture, wireless networking and mobility software for the world's leading retailers, transportation and logistics companies and manufacturers as well as government agencies and providers of healthcare, hospitality and security. More information is available at www.symbol.com.

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Solutions Issue 10 - Littlewoods Installs Symbol Track And Trace System For Enhanced Customer Service

To improve service to customers through up to date information on parcel movements, Littlewoods is currently rolling out an £8 million Track & Trace system across its distribution network.

The system was delivered by Symbol Technologies in partnership with RangeGate providing the mobile application solution.

Littlewoods and Business Express together deliver 200,000 items per day (up to 400,000 at peak times consisting of 2.4M track & trace scans per day). Every year, Littlewoods processes 69 million parcels across a number of brands:



Solutions Issue 10

- Adshel
- Tesco
- Peacocks
- Waitrose
- Littlewoods
- Costco
- London Marathon
- Safeway
- New Products
- H-Hot
- Portable Shopping
 System™



Littlewoods Agency; Littlewoods Index Extra; Littlewoods Index Stores; commercial deliveries via Business Express for companies such as Harrods; and Dial (Arcadia group parcels and Shop! Parcels).

Under their old system, goods were tracked until they left the distribution centre, for onward delivery to the sortation hub where they were split 33 ways for UK depots. The process was

labour intensive, with manual recording and checking of delivery details at every depot against paper lists. Once a parcel had left the depot, there was no way of tracking it.

Explained David Hallett, Group IT Director: "The primary driver for the project was the need to reduce GLIT. An additional driver was the improvement of quality of information to customers for better customer service. If someone rings up with a query about a parcel, we will be able to say exactly where it is in the chain – 'it's on the van and it will be with you in two hours'. We believe we are the only mail order company who can scan parcels and capture a signature at the customer's door. Now we can use system to identify and eliminate delays or other problems in the delivery chain."

The Track & Trace System provides the ability to scan all parcels into and out of any physical location and allows depot supervisors to perform a security check of how many parcels have been loaded onto any given van. In conjunction with the web reporting mechanism, the system provides information on the whereabouts and tracking history of any given parcel, and measures the performance of drivers with respect to successful deliveries v. failure rate, as well as giving information vital to the general management and performance of the depots.



In autumn 1999, David Hallett and his team began a review process to decide on the IT vendor for their new system. Explained David Hallett: "We whittled the list down to three companies – all of which were using Symbol hardware. Symbol recommended the more advanced Palm Top Pilot terminals and they had a big price advantage because of being the equipment manufacturer and we were keen to have a real-time system and Symbol's Spectrum24® wireless local area network fitted best with our technical architecture. Linked to this, they already had a software solution the TaskMaster solution from RangeGate (up and running at Asda and Sainsbury) that could be heavily customised to reflect our requirements."

Phase 1 of the project delivered the ability for call centre staff to query a large database, via a web browser, for information on parcel progress for commercial customers sending high value goods via Business Express. Phase 2 will provide an open web front end to the public for parcel queries. The system runs on a SUN Solaris UNIX platform, utilising Oracle 8i and EMC disks, accessing an Oracle 8I relational database. The server supports about 2,500 Symbol client terminals, collecting scan information as well as customer signatures.

Paramanananan menangan menanga

The RangeGate Symbol TMS TaskMaster software requests data from the Symbol terminals as they gather scan data in real time. It takes the information, manages it and populates extraction tables for reporting to the LRL (Littlewoods Retail Limited) central track & trace system. While drivers are out on the road, the terminals can operate in batch mode and transmit data back to the central system using a dial-up modem cradle.

Each DC or depot has a Symbol Spectrum24 WLAN

allowing the Symbol terminals to operate in real time, sending and receiving information to the LRL via the Symbol TMS software. Commented David Hallett: "TaskMaster TMS required quite a bit of customisation with the emphasis of the application needed changing from a warehouse management system to business

management of distribution, through depots and out to customers. We also needed changes to the reporting system."

The Track & Trace system:

- Goods are physically scanned leaving the distribution centre using the <u>PDT</u>
 <u>6840</u> or the Metrologic overhead scanner.
- Parcels are scanned through the Shaw sortation centre via automatic sorter or manually, using the <u>PDT 6840</u>.
- They are physically scanned into one of 33 depots using the <u>PDT 6840</u> for bulky items, or the mobile overhead scanner for items on the mobile conveyor.
- Early every morning, the van driver scans every parcel sorted to his route onto his van via the <u>SPT 1740</u>. He scans labels for returns requests. The team leader may carry out security check before the van leaves, using his own scanner to provide a discrepancy list. The driver leaves for his delivery round.
- A final scan and signature capture is carried out at the doorstep using an <u>SPT 1740</u>. Parcels are scanned at the doorstep even if the driver is unable to deliver. For a failed delivery, he must enter a reason code from the on-screen menu, or follow instructions on the terminal to leave it with a neighbour or in the garage. Every parcel must be accounted for. If it cannot be delivered, the team leader must scan the parcel back into the depot the same goes for returns and commercial collections.
- Commercial collections are scanned out to the new depot. Returns are scanned and transported to the Shaw hub for redirection to recovery and return to stock.

Owing to physical space constraints and the need for flexibility in terms of use and location, Littlewoods decided they needed a mobile overhead scanner for use with the mobile conveyor used for offloading parcels from trucks into the depot. Symbol spent a lot of time designing a gantry acceptable to Littlewoods, to hold a Metrologic holotrack scanner capable of scanning every size and type of parcel coming down the conveyor. The gantry in use at Warrington is a prototype and Symbol is in the process of manufacturing 33 of the final model for use in each of the depots.



The pilot system, installed at Warrington in September 2000, comprises: 70 x SPT 1740 van driver terminals, 5 x PDT 6840 night sorter guns and 1 x mobile overhead scanner for mobile conveyor belt. The project will eventually be installed across all depots (1 sortation centre, 11 distribution centres, 2 returns centres, 3 Littlewoods call centres, 1 Business Express call centres and 33 Business Express depots). This will represent a hardware investment over 2,000 x SPT 1740s, 302 x PDT 6840s, 33 x mobile overhead scanners, 11 x fixed overhead scanners and 187 x RF access points,

plus associated charging cradles and modems.

Concluded David Hallett: "We were given the green light for the project in December 2000, and we are now in the middle of rolling out to the DCs and depots. We will complete the project by the end of July. Both Symbol our partnering suppliers and LRL have worked very hard to ensure these aggressive timescales can be met. This is one of Littlewoods top ten IT projects and is very high profile inside the company. Customer expectations are much higher than before. They expect fast delivery and accurate information. We are the only mail order company to track and trace right to the doorstep."



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PX install

Paperless Track and Trace

STUDIES

to streamline Southern Africa operations

PX, an independent division of the Transnet family group specialises in the distribution of parcels and containerised commodities utilising rail, road and air transport. PX's network covers the whole of southern Africa including Namibia, Botswana, Zambia and Zimbabwe

Following the privatisation of PX, a comprehensive analysis was done on the existing parcel and container distribution structures and resulted in the implementation of a track and trace system which allowed for accurate data capture, minimal manual effort and accurate management of parcels throughout the delivery cycle.

PX were faced with the challenge of handling approximately 90 million parcels a year, of which numerous were often lost, stolen or damaged. The system was based on repeated scanning of each parcel throughout its movement within the delivery network. Labels containing three detachable linear barcodes printed by the Zebra S500 barcode printer, would be scanned by the Symbol LDT 3800 data terminal to indicate proof of acceptance, tracking status and proof of delivery. Despite significant improvements to the system, some problems still existed, namely.

- The multiple stick-on labels were costly and labour intensive
- Incorrect calculations of tariff and mass amounts were occurring
- The system generated a large amount of paperwork, including a 6-copy document containing shipment information, which often got lost or damaged and sometimes included an illegible hand-written delivery manifest



Despite its successes, the system invited mistakes. PX needed to replace the 6-copy document with a "paperless" environment and to install a more automated scaling system for accurate billing purposes

After thorough analysis, Symbol Technologies recommended a two dimensional symbology called PDF (Portable Data File) 417 to replace the 6-copy document. PDF 417 can store more than 3000 (and, with compression techniques, up to 29 000) characters per symbol and can be read and decoded on site by a scanner or portable data terminal. Data may consist of text, photographs, voice prints, fingerprints, biometric "signatures" or even a computer program - all carried in a symbol the same size as a regular barcode. Up to 50 % of a PDF 417 code can be destroyed without losing any data because of built-in error correction. Shipment information previously stored on the 6-copy document is now contained in a PDF 417 barcode. It includes information such as date of collection; station details; type of service; insurance details, account and billing details; client reference number; sender and receiver information; consignment value, mass and volume; parcel number; and description.

In addition, PX have provided their larger clients such as Pep Stores, Truworths and Toyota with their own Zebra 105S printer and software so that they may enter their consignment data and print the PDF 417 label at their own premises, before the consignment is collected by PX. Once consignments reach the PX depot, all standard size parcels are first scanned by the Symbol LS4800 PDF hand held scanner and then automatically weighed and dimensioned to verify information given by the client and to check for any discrepancies. The central billing system on the host is immediately updated and a more accurate invoice is sent to the client. Non-standard parcels (parcels weighing more than 50 kg), are manually weighed and dimensioned and then scanned by the Symbol PDT 3500 portable data terminal.

The terminal is placed into its docking station and information is downloaded to update the central billing system on the host. The PDT 3500 terminal is also utilised to allocate consignments into cages or hubs and to capture final delivery notices at the destination depot. An electronically produced manifest form is printed and signed by the client upon receipt of the consignment. With no reliance on a network, client information is instantly captured resulting in increased productivity and speedier distribution processes. The PDF417 code is always available and mobile and builds a "paperless" environment. PX revenue is protected through an automated weighing and dimensioning system allowing for more accurate billing and increased savings.

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UPS and Symbol Technologies Backgrounder

FAQ (Frequently Asked Questions):

Question: How long have Symbol and UPS worked together?

Answer: Symbol has been a strategic technology partner of UPS for nearly 15 years. The technology solutions that Symbol has co-developed with UPS are central to the UPS system of picking up, tracking and delivering some 15 million packages and parcels every day. UPS scans nearly 75 million bar codes every day with a Symbol scanning device.

Question: What's new with the DIAD IV (delivery information acquisition device) that UPS announced on April 15, 2003?

Answer: The DIAD IV, co-developed with Symbol, will be deployed to the global network of 70,000+ UPS drivers over the next several years. DIAD IV is a highly rugged device designed to perform in any kind of weather or environment that a driver may encounter. It allows drivers to capture information about package pickup and delivery and includes signature capture on a bright, color screen. In addition to laser bar code scanning capabilities, the device includes three types of wireless communications: wireless LAN (the Symbol Spectrum24® wireless local area network), wide area network (WAN) and Bluetooth. It also includes GPS (Global Positioning Systems) that will allow drivers to verify customer locations.

Question: What is the revenue to Symbol for the DIAD IV project?

Answer: UPS has not announced specific revenue to Symbol however it did go on record that the project would cost \$127 million over the next several years.

Question: Is Symbol involved in other technology projects with UPS?

Answer: Symbol provides the UPS wireless local area network for wireless communications in its 1,700 office buildings, sortation hubs, distribution centers and hubs. Spectrum24 will be fully deployed in 2004 with some 15,000 access points.

The wireless ring scanner (Bluetooth coexisting with WLAN) is also part of the UPS sortation solution where thousands of workers route parcels and packages each night.

Useful Links:

15 April 2003 - UPS to spend \$127M on tri-mode wireless driver terminals http://www.computerworld.com/mobiletopics/mobile/story/0,10801,80369,00.html

15 April 2003 - UPS Drivers to Use Next-Generation Wireless Computer (ups.com press release)

http://pressroom.ups.com/pressreleases/current/0,1088,4287,00.html

 $15 \ \text{April} \ 2003$ - UPS Drivers to Use Next-Generation Wireless Computer (Yahoo version of the UPS press release)

http://biz.yahoo.com/bw/030415/155612_1.html

December, 2002 - UPS Uses WiFi & Bluetooth Together To Manage Packages at Shipping Hubs

http://www.mobileinfo.com/News_2002/Issue47/UPS_WiFi_Bluetooth.htm



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