Product Traceability in the Pharmaceutical Supply Chain:
An Analysis of the Auto-ID Approach

by

Attilio Bellman
PhD in Physics
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Submitted to the Engineering Systems Division in
Partial Fulfillment of the Requirements for the Degree of

Master of Engineering in Logistics

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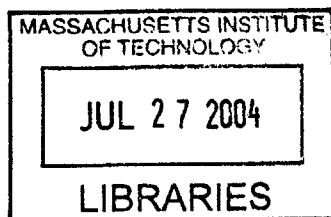
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BARKER

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Abstract

This thesis analyzes how the Auto-ID technology and information infrastructure will
change the management and distribution of pharmaceutical products within the health
care industry by enabling item level product traceability functionality. The complexity of
the health care industry is steadily growing, due to the concurrent increase in medical
knowledge, biomedical technologies, the number of medications and the age of the
population. The key to ensuring the quality, integrity and availability of health care goods
is the ability to track and trace individual items throughout their complete life-cycle from
manufacturing to disposal. Product traceability within the Supply Chain is becoming
increasingly important for pharmaceutical manufacturers because the increasing number
of medications distributed worldwide has led to the proliferation of counterfeit drugs,
product diversions, re-importations and grey markets. Ultimately, the increasing
complexity of the pharmaceutical distribution could affect patient safety. The potential of
the Auto-ID technology and information infrastructure to synchronize the information
and material flow is illustrated using a case study methodology.

Thesis Supervisor: Jim Masters
Title: Executive Director, Master of Engineering in Logistics Program

Acknowledgements

I dedicate this thesis to my parents and to my wife Melissa, and thank them for their love and their full support.

Table of Contents

1 Introduction

Product Traceability or, as it is more commonly called, Track and Trace, is the ability to know the physical location of an item at any time (Track) and the ability to know where the item has been (Trace) in the past. In this thesis "Product Traceability" is synonymous with "Track and Trace". Product traceability constitutes the foundation for a higher level of patient safety by giving the ability to control drug diversions, and counterfeiting of pharmaceutical products. These illegal practices pose a threat to the consumer/patient by introducing potentially dangerous drugs into the market [Donald de Kieffer et al., 2002 & 2003].

The complexity of health care is steadily growing, due to the concurrent increase in medical knowledge, new drug development, biomedical technologies and age of population. More and more individuals undergo medical procedures [Sanna et al., 2002] either preventive or therapeutic, and this increases the number of errors in delivering care and medications [Kohn et al., 2000]. Moreover, the increasing number and types of medications distributed worldwide and the high profit margins associated with pharmaceutical products have led to more counterfeit drugs, diversions, re-importation and grey markets.

US and European government regulators are creating opportunities for the adoption of new technologies in the health care sector to improve patient safety [Kohn et al., 2000]. In particular Product Traceability within the hospital and the whole supply chain together with the integration between hospital internal processes and the distribution processes has bee proven very important for improving patient safety [DRIVE, 2003].

1.1   Scope of the thesis

In this thesis we show how Auto-ID Center's information infrastructure and Radio

Frequency Identification (RFID) technology will improve Product Traceability

capabilities for the pharmaceutical industry by providing the advanced Product

Traceability functionality needed to improve patient safety.

We will examine in detail the supply chain for a specific product and we will explain how

Auto-ID can provide a solution for drug pedigree recalls, returns and shelf life

management and how it can provide better control over diversions, re-importations, grey

markets and counterfeit drugs. The potential of the Auto-ID Center's information

infrastructure is illustrated using a case study methodology.

We will focus, in the thesis, on the capability of tracking and tracing drugs in the

pharmaceutical supply chain, leaving the issue of studying the traceability of medical

equipment and medical devices to future research work.

1.2   The changing regulatory environment

Healthcare in the United States is not immune from safety issues. Between 44,000 and

98,000 people die in hospitals each year, as a result of medical errors that could have

been avoided, more deaths than from motor vehicle accidents (43,458), breast cancer

(42,297) or AIDS (16,516) [Kohn et al., 2000]. In particular, Adverse Drug Events

(ADE), that are clinical events suffered by patients as a result of inappropriate drug therapy management (i.e. administration of drug different from the prescribed one, wrong dosage, prescription of a drug to a patient that is known to be allergic to it, etc), have been identified as the single greatest cause of errors in the hospital setting.

In addition to the cost in human lives, preventable medical errors cost money: The cost has been estimated between $17 and $29 billion per year [Sanna, 2002]. In November 1999, the Institute of Medicine (IOM) published an important article titled *"To Err is Human: Building a safer health system. "* [Kohn et al., 2000]. In this report, IOM lays out a comprehensive strategy by which government, health care providers, industry and consumers can reduce medical errors. Concluding that methods and technology already exist to prevent many of these medical errors, the report sets a minimum goal of 50% reduction in errors over the next 5 years.

In December 2000, Congress appropriated $50 million to the Agency of Healthcare Research and Quality (AHRQ) to support a variety of efforts targeted at reducing medical errors. Efforts under way will include:

- Developing and testing new technologies to reduce medical errors.
- Conducting large-scale demonstration projects to test safety interventions and error-reporting strategies.

The report *"To Err is Human"* prompted the American Government and the European Community to recognize the need for the development and implementation of new technologies in order to address patient safety issues. The capability to Track, and Trace

plays a fundamental role in improving patient safety, in particular when the concept is applied to drugs.

It has been proven that Product Traceability, applied to drug administration within hospitals, can substantially reduce Adverse Drug Events (ADE) [DRIVE, 2003] by allowing to match the right drug, in the right dosage, to the right patient. Reducing ADE, is only one step of the process towards full patient safety. Other important factors include, for example, delivering the right medicine in the right dosage or verifying that the medicine was not counterfeit, or not properly handled within the supply chain.

For example, Patient safety is under scrutiny in Italy as well as in other European countries, Portugal and Belgium in particular. With the Law No 388, 23 (December 2000) [Bollini Law, 2000], the Italian Government is enforcing the traceability of pharmaceutical products by uniquely numbering each item (by using the so called BOLLINI) and it is forcing all the parties in the supply chain to record and archive each number. The applicability of the law has been delayed several times, until June 2004, due to the lack of a technology suitable for the task. Since January 2003 pharmaceutical manufacturers are applying the uniquely numbered BOLLINI, special bar code labels produced by the Italian Mint, to each item but the actual full traceability will start only in June 2004. A full description of the database structure that will supposedly store the track and trace information has not been disclosed to date (June 2003), but it appears that the Italian Government is oriented to establish a Government-managed centralized database for the purpose.

How can Governments improve patient safety? Two important questions have to be answered in order to fully address patient safety issues:

- Where does patient safety start? With the patient, at the Pharmacy, at the Hospital or at the Manufacturing plant?

- How important is the full integration and coordination between the hospital clinical processes and the pharmaceutical supply chain?

1.3 The importance of Product Traceability in healthcare

Product Traceability is the key to improved patient safety because the health care sector, as a whole, is critically dependent on the rapid and accurate communication of extensive information on patient status and medical procedures, as well as on accurate information about pharmaceutical products and their history within the supply chain. We will show how the Auto-ID technology and infrastructure can provide the necessary advanced Product Traceability capabilities that will be of critical importance for developing higher-level functionality that will ultimately improve patient safety, such as:

- **Patient Safety**: Patient safety is the driver of all the laws, regulations and improvements imposed to the healthcare sector. Patient safety is the ultimate concern of Governments, doctors, hospitals, manufacturers, pharmacies and distributors. Clinical processes and the pharmaceutical supply chain have to synchronize to guarantee a better and more secure care to the patient.

11

- **Drug Pedigree:** It is very important to know the history of a drug in the supply chain. Drug pedigree arises from the capability to effectively record the history of a drug, namely, when and where it was produced, who bought and sold it, whether it was properly handled (by recording telemetric information, like temperature and humidity), and whether it is being sold in a legitimate market.

- **Counterfeit Drugs:** Counterfeit drugs are a multibillion dollar problem worldwide. It has been estimated that 5 to 7% of drugs worldwide are counterfeit [FDA, 2003]. The number further increases if we included drugs that are still on the market but are ineffective because they have been mishandled (for example stored at the wrong temperature).

- **Diversions/Re-importation and Grey Market:** Drugs are sometimes diverted form markets where drugs are cheaper to markets where drugs are more expensive [Bureau of Drug Surveillance, 1998]. This affects the revenue of pharmaceutical companies and easies the way of adulterated, mishandled, misbranded and counterfeit medicines into legitimate markets. Diversions, re-importation and grey markets ultimately hurt developing countries: Pharmaceutical companies are reluctant in providing cheaper drugs to poorer countries because companies cannot control illegal re-importation of such drugs.

- **Recalls:** Recalls are usually extremely expensive both in terms of direct costs (transportation, lost sales) and indirect costs (marketing necessary to rebuild confidence in the brand), because recalls are indiscriminate. Companies do not

have the capability to identify what exactly they have to recall and where, in the supply chain, the product that they have to recall is located.

- **Returns**: Distributors and pharmacies do not have the capability to know whether they should accept a return or not because they don't know whether that specific product was sold by them or by a competitor. The inability to track pharmaceutical products by lot number and, more specifically by serial number, introduces additional costs in the supply chain.

- **Shelf Life**: Hospitals, distributors and pharmacies cannot efficiently manage shelf life and expiration date of drugs. This creates huge additional costs because expired drugs or drugs that are about to expire (within 3 or even 6 months from expiration, depending on the company policy) cannot be sold and have to be re-sent to the manufacturer.

1.4   Mass Serialization and Radio Frequency Technology

We think that Product Traceability will inevitably drive mass serialization because only items that are uniquely identifiable can be fully tracked and traced. Mass serialization will drive the adoption of radio frequency technology and of the Auto-ID Center information infrastructure and standardization, because managing such a huge number of unique items will be challenging.

Reading billions of identifiers cannot be handled using bar codes because bar codes require the "line of sight" for identification and because bar codes are a "unidirectional"

way of communicating information. An item cannot be remotely "asked" to communicate information about itself to an ERP system: Its bar code has to be read in order to retrieve information on the object (see section 2).

This "unidirectional" characteristic of bar codes is a huge limitation in the management of shelf life and recalls. A lot of manual work is required to find where the items to recall are located in the supply chain or whether there are any expired items in a warehouse, when using barcodes. In these cases the ability offered by RFID to "inquire" or "ping" the items within the whole supply chain would be extremely beneficial.

The Italian Government proposal to implement full Product Traceability at the item level [Bollini Law, 2000] (see the BOLLINI Law in Appendix I), by applying special bar codes – the BOLLINI – to each pharmaceutical item is receiving a lot of criticism from distributors and pharmacies because reading the bar codes will considerably slow down the distribution process and burden distributors and pharmacists with additional responsibilities.

Criticism has been expressed as well about the information infrastructure proposed by the Italian Government: A Government-managed centralized database. Collecting, sharing and distributing the information related to each item in the whole supply chain poses major strains on the information infrastructure and could hardly be handled with a centralized database. The combination of bar-codes and Government-run centralized database does not seem to be adequate for handling item serialization on such a large scale (1.2 Billion items are handled by Italian Distributors in one year).

Alternative technological solutions have to be found in order to take the concept of Product Traceability to the item level. New ways of handling billions of items are needed and new ways of "interacting" with items have to be explored. RFID coupled with Auto-ID Center's information infrastructure can offer a feasible solution to the problems related to mass serialization and full Product Traceability.

2   *Literature Review*

We performed a thorough review of the published logistics literature. We queried the Council of Logistics Management – CLM – database and the ABI/Inform, an online index to articles in over 1000 business and management journals and magazines. The two resources, combined, give access to about 70,000 publications. The main result of our research is that the field of Product Traceability/Track and Trace in the pharmaceutical industry is unexplored and very little published research work has been done on it.

For example, the Journal of Business Logistics contains only a few articles on the issue. The most relevant article is "The management of the supply chain for hospital pharmacies: A focus on inventory management practices" [Beier, 1995] in which an Economic Order Quantity (EOQ) methodology is compared to current practice to serve as a means of measuring the magnitude of potential savings from revising current inventory strategies.

Some other articles [Mitchell, 1998] approach product traceability by focusing on the reengineering of the IT systems to manage the flow of millions of pages of

documentation as a prerequisite to government approval for product manufacturing and sales, basically considering product traceability as a result a an FDA mandate.

The article "Blockbuster Market [Cottrill, 2001 a]" focuses on the effects of demographic changes and new product development in the US pharmaceutical distribution, from a marketing and category management point of view. Demographic changes coupled with new product development and payment practices will push even higher volumes of pharmaceuticals through the country's drug pipeline over the next few years. For distributors, this means increasing product complexity and fluctuating demand as pharmaceuticals begin to look more and more like consumer packaged goods.

Another article by on Traffic World, "Handle with care" [Cottrill, 2001 b] deals with the new distribution and supply chain systems that will be needed to bring advanced biotechnology products to market.

"Multiple fractures" [Cottrill, 2001 c], deals with how the pharmaceutical supply chain can affect patient safety. Disjoints in the pharmaceutical supply chain are causing drug shortages that force caregivers to look for alternative medications or even go without. There is growing concern that the problem is inflating drug costs and endangering the health and lives of patients.

The interesting aspect of telemetry information during transportation is described in the article "KLM Service Targets Pharmaceuticals" [Barnard, 1999], in which a new KLM service is presented, said to provide an unprecedented degree of environmental control, eliminating variations in temperature and humidity throughout the transportation chain.

On a more general ground, articles on track and trace capabilities are available on companies like UPS or FedEx, but not specific to the pharmaceutical industry. A generic article on shipment track and trace is "Collaboration without chains" [Hickey, 2000]. This article describes the ultimate dream: to manage a company's shipments while away from the office by making track-and-trace capabilities available over a portable device.

The reviewed literature is not sufficient for the development of this thesis because it fails to address the focus itself of the thesis, Product Traceability in the pharmaceutical industry. The research literature that we found is very limited on patient safety issues and completely lacks a European perspective on the issue that we consider important.

The most complete article available, with a European perspective, on patient safety, and on the importance of the integration between the pharmaceutical supply chain and the clinical process within the hospital is "SAFE-ID: Safety Procedures for Identification of Patient and Related Objects,", together with the material on the web site of Project DRIVE, Drugs in Virtual Enterprise [DRIVE, 2003].

Another article important to mention is the article by David L. Brock "Smart Medicine - The application of Auto-ID Technology to Healthcare" [Brock, 2002]. This is the first article describing possible applications of the Auto-ID Technology to the healthcare industry and will be a base on which we want to further build our research.

None of the above mentioned articles, however, address the issue of diversions, recalls, expiration date management and drug counterfeit in a specific way. We will dedicate a section of the thesis on how the application of Auto-ID Technology could be a solution for those problems.

Finally, we did some research on US federal regulations [FDA, 2003, H.R.663, 2003; Florida Law, 2003] and European Regulations [Bollini, 2000; Pharmaceutical Packaging News, 2002] on patient safety and distribution requirements for pharmaceutical products and we discovered a clear tendency from US and European regulators to considering Product Traceability of increasing importance: For instance, the Bollini Law imposes mass serializations and full track and trace at the unit dose, and the Florida law defines the requirements for a more detailed drug pedigree.

2.1 Product Traceability Technology Overview

In Appendix II we list some of the technology providers that offer some sort of Product Traceability or track and trace, in various industries. Most of them use RFID technology for their products, some use new bar code technology.

Most of the interesting technology alternative to Auto-ID that could be leveraged for some product traceability functionality is based on "visual" recognition methods that have been originally developed as anti-counterfeiting technologies [De Kieffer et al., 2002].

Most of these techniques are heavily based on packaging design and, more in general, on graphic design and they work by embedding increasingly sophisticated security features into packaging. For example, some software programs can add complicated elements to the design that are not composed by the dots that typically create digital images. By using

shapes instead of dots these software packages can create patterns that are difficult to scan or reproduce accurately.

The use of special paper is another technique for anti-counterfeiting and product traceability. New to the industry is the use of Radio Frequency (RF) fibers in paper. A growing number of paper manufacturers are preparing to introduce products incorporating RF fibers. The RF signal signature from an array of fibers embedded in the paper could be read and compared to data in a database to identify the type of paper and provide some track and trace functionality.

Holograms are another technique, mostly utilized for anti-counterfeiting but with possible applications to track and trace. Holograms can be fairly sophisticated and difficult to reproduce but the downfall is that they rely on "visual" recognition to be distinguished from fake ones. Although counterfeit holograms may not perfectly resemble the originals, they may be "good enough" to fool the users.

We investigated whether other emerging technologies may provide advanced Product Traceability functionality and whether these technologies were comparable, in the overall functionality and breadth of solution offerings, to the Auto-ID technology and infrastructure. We will describe the ones that, in our opinion, are the most interesting and innovative and we will make a functionality comparison between Auto-ID and these other new technologies.

BTI:

http://www.lynxstreet.com/

BTI is the owner of Reduced Space Symbology, RSS which is a hybrid barcode with one-dimensional and two-dimensional components based on the established UCC/EAN system. RSS is a new form of barcode, developed by the UCC (Uniform Code Council) and EAN (European Article Numbering Association). RSS expands the use of the existing numbering system by adding a packaging designator to the product ID to create a GTIN (Global Trade Identification Number). RSS has been built on the existing UCC/EAN system.

Comments: This is a bar code based technology with all the intrinsic limitations of bar codes (line of sight, mono-directional, etc). Moreover, the information on bar codes are static and bar codes will soon reach a physical space limit.

Stockway:

http://www.stockway.fi/

Stockway has developed a peer-to-peer network that enables companies to share real-time data about products, regardless of the kind of RFID tag used on them [Käekkäinen, 2002]. The company's World Wide Article Information (WWAI) protocol allows companies to store information about a product on a number of computers. Stockway has also developed the Trackway asset-tracking application, which provides security and authentication features that let companies decide who gets to see information related to a particular item. They don't track information as such but where information can be found, in a peer-to-peer model. The World Wide Article Information protocol (WWAI) is an application-level protocol (upon TCP/IP) for distributed article information peer-to-peer networking. It is a generic XML-based protocol which can be used for many tasks

beyond its use for article information. The WWAI protocol is designed to create and manage product centric distributed networks. The WWAI protocol fulfils a key element in creating and maintaining a network of different organizations or internal business units sharing real-time information about physical products.

Conclusion: Interesting technology but it requires the whole community participating to the supply chain to accept its standards. Moreover, the peer-to-peer architecture fails to properly handle file versioning making it cumbersome to know where is the most update information.

SPHINX:

http://www.sphinx-system.com/index_e.htm

The main scope of the SPHINX™ system is to provide the ability to distinguish quickly and simply an original product from a counterfeited one by using bar code technology and uniquely numbering each item.

The SPHINX system assigns to each item an individual numeric or alphanumeric security number, which is generated exclusively by SPHINX system. During the production process each product or its packing will be marked with an individual SPHINX security number by accessing the SPHINX system.

The SPHINX system assigns an individual and unique random numeric or alphanumeric security number, administered by a central database, to every product. Such a number is applied during the production process on the package or a sticker/label of the product. Every security number can be used only once.

21

The product marking consists of three elements. Firstly the SPHINX Logo, which gives the consumer a clear graphic indication of product protection. Secondly the numeric or alphanumeric SPHINX security number as a barcode. Thirdly the security number which is applied in addition to the bar code as a character sequence, so that the authentication of the product does not depend on a bar code scanner.

SPHINX™ Label with linear bar code

05487186431 5H7zuTf7
Authentication: www.sphinx-system.com

SPHINX™ Label with 2D bar code

0648718643
15H7zuTf7
Authentication: www.sphinx-system.com

The product is therefore followed and monitored as it makes its way from the manufacturer, supply chain and ultimately to the consumer by means of a central database, used as a trust center, providing a complete track and trace capability solution.

Conclusions: Interesting technology but still bar code based. Moreover, It is a proprietary non standardized solution that will require the whole supply chain to adhere to the same technology. Not enough information is provided on the SPHINX web page on its centralized database (how data is handled and supported and how data is

exchanged) to allow any more informed judgment on their capability to perform track and trace.

2.2 Auto-ID Technology Overview

In the following sections we will briefly describe the Auto-ID technology and infrastructure. For a deeper understanding, please refer to the Auto-ID publications on the Auto-ID web site: http://www.autoidcenter.org/

2.2.1 A deeper look at the new network: Auto-ID

Automatic identification, or Auto-ID for short, is the broad term given to a host of technologies that are used to help machines identify objects. Auto identification is often coupled with automatic data capture.

Imagine that each object on earth had some sort of intelligence that enabled it to respond to the needs of the Supply Chain in real time so that, for example, it could be loaded only on the right truck or plane, it could send replenishment orders to its manufacturer and, at the end of its journey, it could recycle itself according to the manufacturer's and law's specifications.

The Auto-ID Center is developing the technology and the infrastructure that can give objects the ability to interact with each other and with human beings and eventually to behave accordingly to pre-defined rules.

23

The Internet connects computers to one another. The Auto-ID Center aims to develop a network that connects computers to objects, boxes of laundry detergent, pairs of jeans, airplane engines, by creating the "Internet of things". This includes affordable hardware, network software, protocols, and languages for describing objects in ways computers can understand. The system will be based on open standards.

RFID is a generic term for technologies that use radio waves to automatically identify individual items. There are several methods of identifying objects using RFID, but the most common is to store a serial number that identifies a product, and perhaps other information, on a microchip that is attached to an antenna (the chip and the antenna together are called an RFID transponder or an RFID tag). The antenna enables the chip to transmit the identification information to a reader. The reader converts the radio waves returned from the RFID tag into a form that can be passed on to computers that can make use of it. The Auto-ID Center has chosen to focus on "passive" RFID tags, i.e., tags that are not powered by internal batteries but by the electromagnetic energy that comes from the reader. This type of tag is very simple to produce and its cost is low.

We will show that by assigning a unique number (see the following section on the Electronic Product Code – EPC) to each pharmaceutical product, and by leveraging the Auto-ID infrastructure, we will be able to develop advanced Product Traceability capabilities for the health care sector that will ultimately allow to reduce drug counterfeiting and diversions and to effectively manage recalls and returns.

AUTO-ID SYSTEM

- Standards
  ePC, PML
- Automatic data capture
  Tags & Readers
- Network
  ONS & Savant
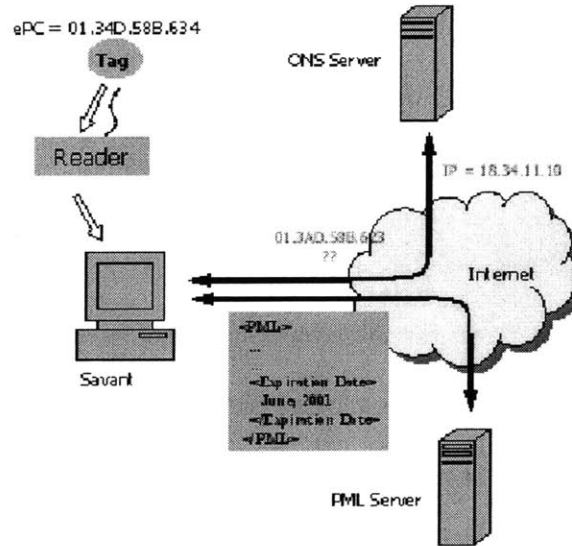
© 2002 Auto-ID Center

2.2.2 *The Electronic Product Code – EPC*

The Auto-ID Center has proposed the introduction of the so called EPC, Electronic

Product Code, as the next standard for identifying products. The EPC contains a number

that identifies each item in the Supply Chain. The EPC by itself carries no more

information about a product than a car's license plate carries about a car. Computers need

a way to associate the EPC with information stored somewhere else about the unique

item. To help computer systems find and understand information about a product, the

Auto-ID Center has developed some new technologies and standards (see the section on

the Object Name Service, ONS and Physical Markup Language, PML).

Like a bar code, the EPC is divided into numbers that identify the manufacturer, product, version and serial number. The EPC is the only information stored on the Auto-ID RFID tag's microchip. This keeps the cost of the tag down and provides flexibility, since an infinite amount of dynamic data can be associated with the serial number in a database linked through a network.

The goal is not to replace existing bar code standards, but rather to create a migration path for companies to move from established standards for bar codes to the new EPC. To encourage this evolution, the Center has adopted the basic structures of the Global Trade Item Number (GTIN), an umbrella group under which virtually all existing bar codes fall. There's no guarantee that the world will adopt the EPC, but the Auto-ID Center's proposal already has the support of the Uniform Code Council (UCC) and European Article Number (EAN), the two main bodies that oversee international bar code standards.

2.2.2.1 How the EPC works

The EPC is a number made up of a header and three sets of data, as shown in the figure above (Figure 2.2.2.1). The header identifies the EPC's version number - this allows for different lengths or types of EPC later on. The second part of the number identifies the EPC Manager - most likely the manufacturer of the product the EPC is attached to. The third, called object class, refers to the exact type of product, most often the Stock Keeping Unit - for example "Acetaminophen, 120 caplets, 500 mg each, US market". The fourth is the serial number, unique to the item - this tells us exactly which bottle of

"Acetaminophen, 120 caplets, 500 mg each, US market" we are referring to. This makes it possible, for example, to quickly find products that might be nearing their expiration date or that might have been diverted.

EPC Number - Figure 2.2.2.1

ELECTRONIC PRODUCT CODE TYPE I

01 . 0000A89 . 00016F . 000169DC0

Header   EPC Manager   Object Class   Serial Number
8 bits   28 bits   24 bits   36 bits
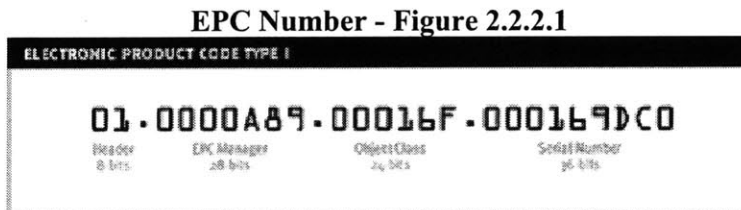
2.2.2.2 Types of EPCs

The Auto-ID Center has proposed the EPC number of 96 bits. A 96 bits number is a compromise between the desire to ensure that all objects have a unique EPC and the need to keep the cost of the tag down. The 96-bit EPC provides unique identifiers for 268 million companies. Each manufacturer can have 16 million object classes and 68 billion serial numbers in each class, more than enough to cover all products manufactured worldwide for years to come.

2.2.3 Object Name Service

The Auto-ID Center's vision of an open, global network for tracking goods requires some special network architecture. Since only the Electronic Product Code is stored on the tag, computers need some way of matching the EPC to the information about the associated item. That's the role of the Object Name Service, ONS. ONS points a computer to an

27

address on the Internet where information about a product is stored. The concept is based on the Domain Name Service, which points computers to the address of particular Web sites on the World Wide Web. ONS basically tells a company's computer systems that all the information about product 1-2345-67890 is stored in a file on a computer located at a specific Internet address. The DNS starts with a name and points to a web address, the ONS starts with a number and points to a name.

When an interrogator reads an RFID tag, the Electronic Product Code is passed on to a Savant (see below). The Savant, in turn, goes to an ONS on a local network or on the Internet to find where information on the product is stored. ONS points Savant to a server where a file about that product is stored. That file can then be retrieved by the Savant, and the information about the product in the file can be forwarded to a company's inventory or supply chain applications.

2.2.4 Physical Markup Language – PML

The Electronic Product Code identifies individual products, but all the useful information about the product is written in a new, standard computer language called the Physical Markup Language (PML) [Brock ate al. 2001; Floerkemeier et al., 2002] based on the widely accepted eXtensible Markup Language (XML). Because it's meant to be a universal standard for describing all physical objects, processes and environments, PML will be broad and will cover all industries. The is to start with a simple language to encourage adoption. PML will evolve over time, just as HTML, the basic language of the Web, has become more sophisticated since it was introduced.

28

2.2.4.1 Types of PML data

In addition to product information that doesn't change (such as material composition), PML will include data that changes constantly (dynamic data) and data that changes over time (temporal data). Dynamic data in a PML file might include the temperature of a shipment of vaccines or a patient's blood pressure. Temporal data changes discretely throughout an object's life. One example is an object's location. By making all of this information available in a PML file, companies will be able to use information in new and innovative ways. A company could, for instance, set triggers so that the price of a product falls as its expiration date approaches. Third party logistics providers could offer service-level contracts indicating that goods will be stored at a certain temperature as they are transported.

2.2.4.2 PML Server

PML files will be stored on a PML server, a dedicated computer that is configured to provide files to other computers requesting them. PML servers could be an extension of a company's legacy database system. The PML server handles the data security and selectively exposes only certain subsets of the data to authenticated users with particular roles/relationships.

2.2.5 Savant

In a world where every object has an RFID tag, readers will be picking up a continual stream of EPCs. Managing and moving all this data is a difficult problem that must be overcome for any global RFID network to be of value. The Auto-ID Center has designed software technology called Savant to act as the nervous system of the network.

2.2.5.1 Distributed architecture

Savant is different from most enterprise software in that it isn't one overarching application. Instead, it uses a distributed architecture and is organized in a hierarchy that manages the flow of data. There will be Savants running in stores, distribution centers, regional offices, factories, perhaps even on trucks and in cargo planes. Savants at each level will gather, store and act on information and interact with other Savants. For instance, a Savant at a store might inform a distribution center that more product is needed. A Savant at the distribution center might inform the store Savant that a shipment was dispatched at a specific time.

2.2.5.2 Data storage

Existing databases can't handle more than a few hundred transactions a second, so another job of the Savants is to maintain a real-time in-memory event database (RIED). In essence, the system will take the EPC data that is generated in real time and store it

intelligently, so that other enterprise applications have access to the information, but databases aren't overloaded.

2.2.5.3 Task management

All Savants, regardless of their level in the hierarchy, feature a Task Management System (TMS), which enables them to perform data management and data monitoring using customizable tasks. For example, a Savant running in a store might be programmed to alert the stockroom manager when product on the shelves drops below a certain level.

2.2.6 The Basics of RFID Tags

An RFID tag is made up of a microchip attached to an antenna. There are different kinds of tags for different applications, and we'll explain these in this section. One of the keys to making RFID useful for tracking individual items is dramatically reducing the cost of the tags.

2.2.6.1 Active versus passive Tags

Active RFID tags have a battery, which is used to run the microchip's circuitry and to broadcast a signal to a reader (the way a cell phone transmits signals to a base station). Passive tags have no battery. Instead, they draw power from the reader, which emits

31

electromagnetic waves that induce a current in the tag's antenna. The tag is only powered in the presence of the electromagnetic field generated by the reader.

Semi-passive tags use a battery to run the chip's circuitry, but communicate by drawing power from the reader. In some cases the battery is rechargeable, using electromagnetic waves transmitted from the reader. Active and semi-passive tags are useful for tracking high-value goods that need to be scanned over long ranges, such as railway cars on a track, but they cost several dollars (between $2 and $100), making them too expensive to put on low-cost items. The Auto-ID Center is focusing on passive tags, which cost under 10 cents. Their read range isn't as far - less than ten feet vs. 100 feet or more for active tags - but they are far less expensive than active tags and require no maintenance.

2.2.6.2 Read-write vs. read-only

Chips in RF tags can be read-write or read-only. With read-write chips, you can add information to the tag or write over existing information when the tag is within range of a reader, or interrogator. Read-write tags are useful in some specialized applications, but since they are more expensive than read-only chips, they are impractical for tracking inexpensive items. Some read-only microchips have information stored on them during the manufacturing process. The information on such chips can never be changed. Another method is to use something called electrically erasable programmable read-only memory, EEPROM. With EEPROM, the data can be overwritten using a special electronic process. Auto-ID recommends Write Once Read Many WORM tags.

2.2.6.3 Control

Once Auto ID data is linked to related PML information via a network, the next important issue relates to what decisions should be made on the basis of this information and to what extent the actions that drive physical operations might be influenced. Whether it is in manufacturing, distribution, retail or domestic use, the process of adjusting operating conditions in order to meet desired requirements is known as "control." For example, in manufacturing, this might refer to the optimal maneuvering of a robot to achieve the best packing sequence for a packaging line.

The Auto-ID Center's vision is of a world where smart products can interact with machines without human involvement, and hence can influence the manner in which they are produced, moved, sold or used. For instance, a smart syringe could be able to read the tag of the drug to be infused, verify the drug type and dosage, check the doctor prescription for this patient and stop the infusion if the information does not match.

2.2.6.4 Decisions

The first step, of course, is for a computer or other machine to recognize an object. Our core technology- the EPC, ONS and PML file - make that possible. The PML file may also contain instructions, or rules, about how the drug should be infused. But there has to be a set of protocols to follow in order that the drug and the syringe can "converse" effectively.

Figure 2.1 – Technology Overview
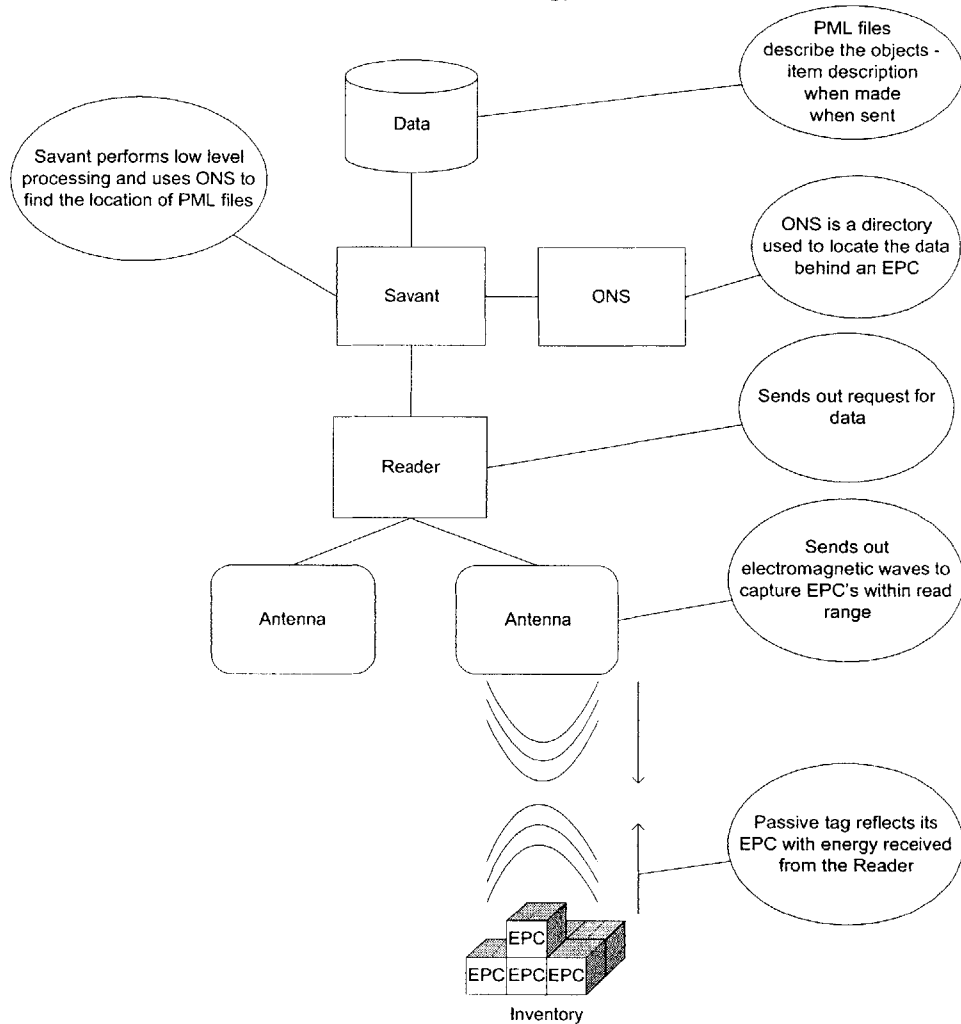
Adapted from APICS Article [Dinning et al., 2003]

2.3 Comparison between Auto-ID and other technologies

The following tables summarize Auto-ID capabilities (Table 2.1) and compare the Auto-ID technology and infrastructure to the above mentioned alternative technologies (Table 2.2).

34

LEGEND:

- **No Line-of-Sight Identification:** The capability to identify an object without the need for a "visual" reading. For example, the bar code has to be visible to the laser in order to be read while RFID does not (RFID can read tags inside closed cartons)

- **Ubiquitous Unique Identification:** The capability to distinguish between items otherwise identical (for example by using a unique identifier like the EPC). Concept related to Mass Serialization. Ubiquitous means that is accepted by all the users (not proprietary)

- **Real-Time Visibility:** Any item can be found within the whole supply chain, in real time.

- **Traceability:** Full Product Traceability, i.e., the capability to locate items at any time and to know/record where items were in the past.

- **Granularity:** The capability to handle single items (a vial, a blister, a carton, etc)

- **Bi-directional Information Flow:** Information can flow from the object to some ERP system, or vice versa, an ERP system could interrogate an object.

Table 2.1: Auto-ID Capabilities

	Tag / Readers	EPC	ONS	PML
No Line-of-Sight Identification	X			
Unique Identification		X		
Real-Time Ubiquitous Visibility	X		X	X
Traceability		X	X	X
Granularity	X	X		
Bi-directional Information Flow	X	X	X	

Table 2.2: Comparison among technologies

	Auto-ID	Stockway	SPHINX	BTI
No Line-of-Sight Identification	X			
Ubiquitous Unique Identification	X			
Real-Time Visibility	X			
Traceability	X	X	X	
Granularity	X	X	X	X
Bi-directional Information Flow	X			

NOTE: Auto-ID is the only technology/infrastructure capable to satisfy all the necessary requirements for full Product Traceability functionality, fulfilling all the 6 criteria.

3 Methodology

The starting point for this thesis has been, as stated in section 2, a thorough research of the published literature. Product traceability in the pharmaceutical industry is a new line of research for the Auto-ID Center and few partially related articles have been written by Auto-ID researchers [Floerkemeier et al., 2002; Milne, 2002 a & b]. We will refer to the numerous articles published by the Auto-ID Center for a more general overview of the technology [Dinning et al., 2003].

36

Most of the information reported in Section 4 is based on interviews. We started by visiting the San Raffaele Hospital in Milan and by interviewing the team that managed the DRIVE, Drugs in Virtual Enterprise [DRIVE, 2003] European-funded project where we learned about patient safety within a hospital and about the importance of integrating the hospital clinical processes and the pharmaceutical supply chain. In this occasion we could interview top managers of major international pharmaceutical companies and Italian distributors.

After the visit to Italy we focused on the US market. We interviewed 5 drug manufacturers, 1 pharmacy and reverse logistics company, 3 drug distributors, 3 organizations related to pharmaceutical distribution and healthcare, 3 hospitals and some consulting companies. We asked them to define the most compelling issues in the pharmaceutical supply chain and then interviewed them on such issues. We interviewed a very diverse group of managers, directors and vice presidents, belonging to several functions within each organization:

- supply chain
- warehousing
- distribution
- store replenishment
- reverse logistics
- purchasing
- public relations
- marketing
- manufacturing
- packaging
- finance
- legal

This wealth of information allowed us to reach a deep understanding of the complete

pharmaceutical supply chain from the manufacturing site to the final patient. Our

interviewees identified drug pedigree, diversions and grey market, counterfeiting, shelf

life management and patient safety as the most important issues that needed additional

research. Such information helped us to pinpoint the main problem that underlines all the

above mentioned issues: The need for advanced Product Traceability and the need for

accurate information about the supply chain and the location of products.

The core of the thesis is based on a case study, done by interviewing several high

managers at a major pharmaceutical company to prove that Auto-ID technology and

infrastructure can provide the advance Product Traceability functionality necessary to

offer a solution for drug pedigree, diversions, counterfeiting, shelf life management,

patient safety and all the above mentioned issues.

We had the chance to spend a lot of time with many directors of this major

pharmaceutical company, to visit their manufacturing lines, their warehouses and their

distribution centers and to engage in several brainstorming sessions about Auto-ID and

ways to implement the Auto-ID infrastructure for this particular supply chain.

4 Data and Results

We will present the results of our research, by referring to an actual distribution model for a specific marketed drug.

4.1 Manufacturing and Distribution Model

We will study Product Traceability within the frame of a very specific supply chain. In the scenario under examination, Manufacturer M sells product MD01, a drug in vials. The drug is sold in kits of 4 vials each, corresponding to a complete therapy for one patient, for one month. The kits are sold under medical prescription and distributed through a predefined third party distributor. The third party distributor, ships the kits to hospitals, clinics or directly to the final patient.

4.2 Supply Chain Participants

The supply chain for this product is located in the United States.

Product MD01 – Sold in KITS of 4 vials

1. **Manufacturer M-API** – The manufacturing plant that produces the Active Ingredient in bulk.
2. **Manufacturer M**: The manufacturing plant where the final KIT is assembled.
3. **Distribution Center DCM** – DCM belongs to Manufacturer M and distributes the product to the Dispensing Company.

4. **Contract Manufacturer CM** – The third party manufacturing plant where the Active Principle is put in the vials.

5. **Dispensing Company D** – Third party distributor. Handles the distribution to the final customer. Dispensing Company D will only deliver the product to hospitals or patient's home. MD01 can only be sold under medical prescription.

6. **Hospital H, Patient P** – The final customers. They will receive the product via secured shipments that require signature at delivery.

7. **Third Party Vendors TPV** – The vendors that will provide Manufacturer M with additional items that will be added to the KIT.

8. **Third Party Tagged Labels and Packaging Vendors TLV** – The vendors that will provide to the parties in the supply chain properly RFID-tagged labels and packaging.

We will discuss the flow of physical goods and related information for this particular model and we will provide a high-level explanation of how Auto-ID can provide advanced Product Traceability capabilities.

4.3 Manufacturing and distribution: Physical Process

In this section we provide a high-level description of the manufacturing and distribution process and we describe the movement of physical goods within the supply chain. An important concept that we want to point out in this section, is that the status (or "identity") of the physical goods changes during the process within the supply chain (please refer to Figure 4.2).

For instance, from the point of view of the Active Ingredient Manufacturer, the physical good is a bulk chemical with a certain name, composition, lot number and an expiration date. For the carrier that moves the goods from the Manufacturer to the Contract Manufacturer the physical good is a shipment, that could be envisioned as an "aggregation" of barrels, pallets, documents, etc. The "identity" of the physical good changes again at the Contract Manufacturer: The Contract Manufacturer fills vials and "assembles" 2 vials in 2-vial cartons so from its point of view, the physical good is a finished product. The example could continue up to the patient's home where the patient break-bulks the KIT, disassembling all the parts, in order to use a single vial.

4.4   Aggregation and Inheritance

Although the physical "identity" of the goods changes during the manufacturing and distribution process due to physical "aggregation/de-aggregation" of the goods, from a Product Traceability point of view all these "identities" are logically linked. Even though the patient purchases "only" a KIT with 4 vials, the patient is actually purchasing a whole manufacturing and distribution process because each item in the KIT has "inherited" its physical and logical characteristics from the process.

Each vial contains a specific active ingredient, with a specific lot number and expiration date, manufactured at a specific plant and it has been shipped on a certain truck, at a certain temperature on a certain date. The quality of the vial depends on all the above mentioned factors.

We will show in this thesis that Product Traceability is based on two concepts:

- **Data Aggregation:** Data aggregation is the logical equivalent of item aggregation or assembly. A shipment is an assembly of cartons, pallets and documents and each of these elements can be represented by the set of data that describe it. Ultimately, the shipment number, represents the aggregation of each physical sub-assembly (number of cartons, weight and measures, number of vials in each carton) and logical sub-assembly (lot number of the active principle, temperature of the vials, manufacturing process details, etc.)

- **Data Inheritance:** Data inheritance represents, in a sense, the history of the data. In order to reconstruct the history of an item, we have to make sure that at each "identity" change, the proper information is carried over from parent to child. By combining data inheritance with data aggregation, we will be able to reconstruct the detailed history of each item.

Data aggregation and data inheritance drastically reduce the number of necessary readings at each point of the supply chain. As an example from the supply chain under study, we can safely say that there is no need for a complete reading of all the vials that are on a pallet. Provided that the pallet is sealed and has not been tampered, the only necessary reading would be the pallet EPC or, at most, the KIT EPC. By inference (aggregated data) it would be possible to know what 2-vials cartons and what vials are in the pallet.

For a visualization of the concept of physical and logical aggregation, please refer to Figure 4.1, where we described the aggregation process between the Manufacturer M – API and the Contract Manufacturer CM.

Figure 4.1: Example of Physical and Logical Aggregation
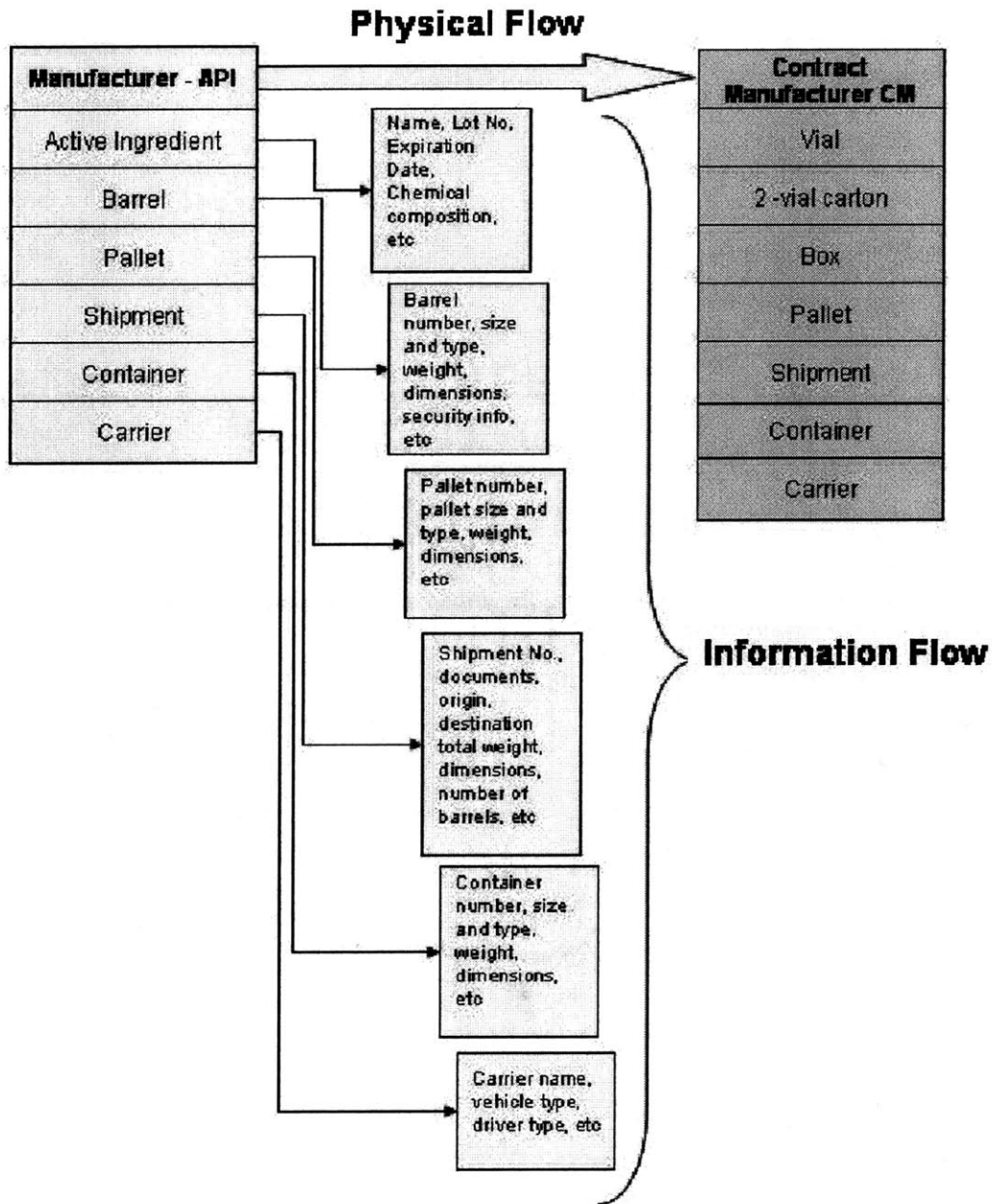
Data aggregation and data inheritance are a direct consequence of the information infrastructure that the Auto-ID Center has built. The Auto-ID Center has done a lot of research on the information infrastructure and very important articles have been published on how Savant, EPC, PML and ONS work together to make the Product Traceability possible [Floerkemeier et al., 2002; Milne, 2002 a & b; Chang et al., 2002].

We leave the technical details to the published literature and we limit ourselves to stress that the Auto-ID information infrastructure and the standardization guidelines that the Auto-ID Center is providing are a key factor for effective Product Traceability. We propose a mechanism for full Product Traceability that can ultimately provide a trustable, reliable, checkable product *pedigree* (see section 1 and Appendix I) with a detailed description of where the product has been, for how long, on what truck it was moved, at what temperature and so on.

4.5   *Physical Process Flow*

We describe the process flow for the physical good within the specific supply chain under study, described in section 4.1. Please refer to Figure 4.2.

Figure 4.2: Manufacturing and Distribution Physical Process
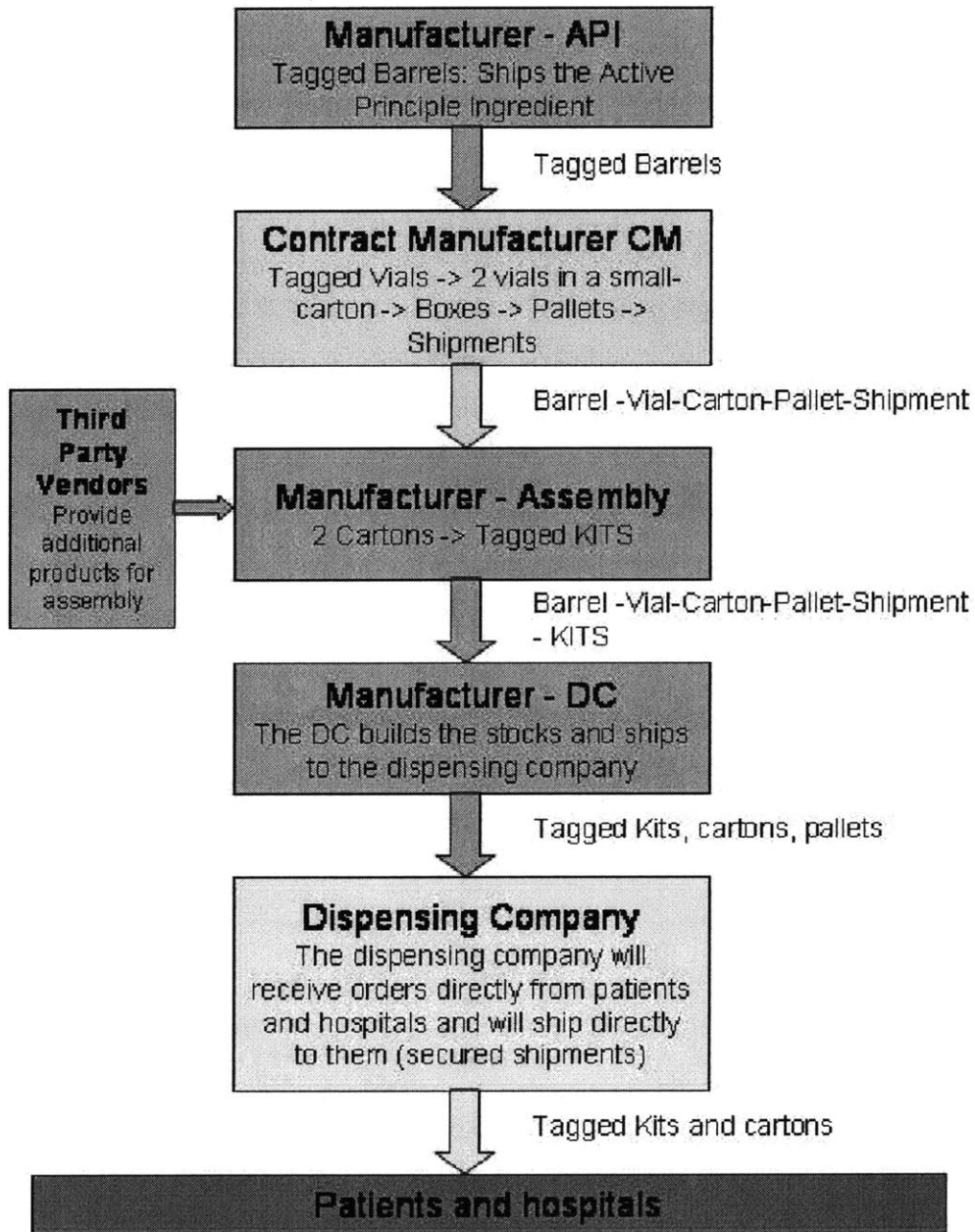
1. The active ingredient is manufactured by Manufacturer M-API in a single plant.

2. M-API then tags the barrels containing the active ingredient using a RFID tag and ships the barrels to the CM

3. The TLV vendors will send proper labels and packaging/vials (with embedded RFID) to the CM

4. The Contract Manufacturer CM fills the vials with the active principle. Each vial will have a RFID tag with an EPC assigned by Manufacturer M.

    a. Inheritance Process: Each vial will inherit the information of the active principle. The EPC of each vial will be linked to the EPC of the bulk active principle (API) in the vial so that API Lot #, NDC #, Expiration Date and other useful information will be passed to the vial-EPC.

5. The Contract Manufacturer CM will put the vials into small-cartons of 2 vials each.

    b. Assembly Process: Each small-carton will have an EPC assigned by Manufacturer M. The 2 EPCs of the 2 vials, will be assembled under one EPC, the 2-vial carton EPC.

6. The Contract Manufacturer CM ships the cartons to Manufacturer M by secured truck shipment. The small-cartons are shipped in boxes.

    c. Aggregation Process: The BOX EPC will aggregate multiple small-cartons EPCs. Boxes will be shipped on pallets. Each pallet EPC will aggregate multiple Box-EPCs.

    d. Aggregation Process: Multiple pallets are consolidated in shipments. A shipment could be a full truck load. Information on the shipment like number of pallets, Bill of Lading number, origin and destination, invoice number, truck and driver ID, etc, can be aggregated under the shipment EPC number [Milne, 2002 a and b].

7. Manufacturer M will assemble the KITS by putting 2 small-cartons in a KIT and by adding additional non-tagged items from TPV.

8. Each Kit will be tagged and will be assigned an EPC by the Manufacturer M.

e. Assembly Process: 2 small-cartons of 2 vials each are put in a KIT. The KIT EPC will aggregate the EPCs of the 4 vials that are aggregated under the EPCs of the 2 small-cartons.

9. Manufacturer M will package the kits, consolidate them into pallets and then ship them to its own Distributor Center DCM. The product is manufactured to forecast and the DCM will accumulate inventory to guarantee regular shipments to the Dispensing Company D. The pallets will be tagged and each pallet will have its own EPC.

    f. Aggregation Process: the KITs will be palletized so the pallet EPC will aggregate the KIT EPCs.

    g. Aggregation Process: Multiple pallets are consolidated in shipments. A shipment could be a full truck load. Information on the shipment like number of pallets, Bill of Lading number, origin and destination, invoice number, truck and driver ID, etc, can be aggregated under the shipment EPC number.

10. The Distribution Center DCM ships the KITs to the Dispensing Company D. DCM keeps constant the replenishment to the Dispensing Company D.

    h. Aggregation/De-Aggregation Process: Shipments are de-aggregated into single pallets and then re-aggregated into new shipments to the Dispensing Company D. New shipments will be assigned a new EPC number by the Distribution Center DCM.

    i. Inheritance Process: Each new shipment from the DCM to the Dispensing Company D inherits the information of the shipments from the Manufacturer M to the Distribution Center DCM. Pallets that came from Manufacturer M on different multiple shipments can be consolidated into one new shipment to the Dispensing Company. The relationship between the new and old shipment will be maintained.

11. The Dispensing Company D will do break-bulk of the shipments into single KITs. This company has the pharmacy license to distribute medicines and they will deliver to the final customer, hospital, clinic or patient.

j. De-aggregation Process: Dispensing Company D will ship single KITs to the final hospital, clinic or patient.

12. The Dispensing Company will receive the prescription from a doctor. MD01 is sold only with a prescription from a doctor and is not sold through pharmacies, but only through a direct order from the doctor to the patient, hospital or clinic. The dispensing company will send the product directly to the patient's home or to the hospital.

13. The Dispensing Company D links each KIT EPC number to the Doctor prescription / order number, the doctor and the patient identification numbers.

14. Manufacturer M wants to track only until the dispensing company. The dispensing company will have to record on their PML Server the exact information of where they will ship the drug, the prescription number, the doctor name, the clinic name (if applicable) and the patient name. These shipments will be controlled shipments. The receiver has to sign for it, at receipt for full Proof of Delivery (POD).

4.6   Manufacturing and distribution: Information Process

We will discuss in this section the flow of information within this supply chain.

4.6.1   Data pre-positioning

The flow of information within the supply chain is as important as the flow of goods. In particular, the information flow between two physical locations or, in general, two different entities in the supply chain (for example between departments, warehouses, plants or carriers) has to be synchronized with the flow of goods.

In order to simplify the synchronization process and in order to guarantee data availability and speed in the readings, we introduced the concept of *pre-positioning of the data* [Milne, 2002 a].

As an example to explain the concept, let's consider the data regarding the shipments between the Contract Manufacturer CM, which fills in the vials, and the Manufacturer M – Assembly, that assembles the KIT.

As explained in points 5 and 6 of the physical process, the Contract Manufacturer CM will perform a physical/logical "aggregation/assembly process" by shipping 2 vials, that are in 2-vial cartons, that are in boxes, that are on pallets that belong to shipments. Each shipment is represented by a shipment number, a Bill of Lading number, the number of pallets, an invoice number, an origin and destination, a driver and truck ID and so on (see Figure 4.1).

As explained in the Technology Overview session, each object is identified by a unique number, the EPC number, and this number allows, by means of the ONS, to retrieve the specific information about the object or entity (being it a vial, a carton, a pallet or a shipment) [Milne, 2002 a and b]. The information is stored on the Internet and not on the object itself.

Since the synchronization of goods and information is very important, the Contract Manufacturer CM will send (pre-position) to the Manufacturer M a set of data, by sending PML files, containing all the information regarding the objects to be received, i.e. the EPCs of all the vials, cartons, pallets, shipments and documents. Additional

information is sent together with the EPCs, in order to allow Product Traceability, for example:

- Location of provenience
- Location of destination
- Time stamps
- Company names
- Telemetry information

The pre-positioning of the information streamlines the receiving process at the dock of Manufacturer M because Manufacturer M can receive against a set of data that is a complete list of what it should expect.

From a product traceability standpoint the location information is extremely important because it provides:

- Past position of the goods (where the goods came from)
- Present position of the goods (where the goods are now)
- Future position of the goods (where the goods will be shipped)
- Time stamps (where goods were and when)

4.6.2 Information flow between Manufacturer M – API and CM

Manufacturer M – API manufactures the Active Principle and ships it to Contract Manufacturer CM in barrels. Manufacturer M – API puts the Active Principle in barrels and assigns an EPC number to each barrel. The EPC of each barrel, will link together all the following information:

a. Active Principle name and composition

b. Production cycle and time

c. Lot Number

d. Expiration Number

e. Manufacturing plant name

f. Manufacturing plant location

g. Process information

h. Other

At some point in the process (daily, weekly etc.), Manufacturer M – API ships the barrels to Contract Manufacturer CM. A shipment number is created, barrels are assigned to pallets and pallets are assigned to the shipment together with proper documentation. Manufacturer M – API pre-positions at the Contract Manufacturer CM information regarding the shipment and its content.

The Active Principle EPC number is now linked to the EPC number of the shipment from Manufacturer M – API to Contract Manufacturer CM, by the aggregation process of API into barrels, into pallets into single/multiple shipment/s. The aggregation process, done at the PML server level, links the shipment information to the product information. The shipment EPC number will link the following information:

i. Location at origin

j. Location at destination

k. Transportation mode (ocean, air, truck, etc.)

l. Shipment date

m. Shipment number

n. Document numbers

o. Document types

p. Weight (gross, net, etc.) and measurements

q. Unit of measurements

r. Number of barrels and pallets

s. INCOTERMS (FOB, CIF, DDU, etc.)

t. Telemetry information (temperature, humidity, etc)

u. Other

The concept of aggregation allows the Manufacturer M to access, by reading the EPC number of a pallet, all the information on the shipment and its content (the info is stored on the PML server):

- Where the pallet is coming from
- How many barrels are on the pallet
- Where and how the Active Ingredient was produced (process information)
- The Lot # and Expiration Date of the Active Ingredient
- Telemetry information, for example humidity and temperature during the shipment
- Other

In particular, the pre-positioning of the data will allow an accurate matching of the readings with what Contract Manufacturer CM should expect. Contract Manufacturer CM will know exactly the number of pallets, cartons and vials that it is supposed to receive and will know all the EPC numbers of each pallet, carton and vial. The receipt is done against a complete list of information so exceptions could be spotted and resolved.

4.6.3 Information flow at Contract Manufacturer CM

The Contract Manufacturer CM receives the barrels with active principle and checks the accuracy of the shipment against the pre-positioned information. Any discrepancy can be

spotted and resolved. The main duty of the Contract Manufacturer CM is to put the Active Principle into the vials and to pack the vials into 2-vial cartons. Finally it ships the cartons in boxes on pallets to the Manufacturer M.

In our model we will assume that the Contract Manufacturer CM receives vials and 2-vial carton packages already tagged with a RF tag from a third party vendor. This assumption implies the need of a control mechanism to guarantee the validity of the EPC used and the control by Manufacturer M, the issuing party, over the process.

4.6.4 EPC reconciliation: Validation of used EPCs

This process allows Manufacturer M to know which vials and cartons EPCs have been used and allows to validate the authenticity of the EPC on the tags. The process streamlines the reconciliation of objects and EPCs and enforces full control over the used EPCs, eliminating counterfeiting (see Figure 4.3):

1. Manufacturer M assigns a lot of EPCs to the vial vendor and a different lot to the 2-vial packaging vendors (Third Party Vendors – TLV)
2. Vendors embed tags in the vials/packaging and write the EPC number to the tag
3. Vendors ship the vials/packaging to Contract Manufacturer CM and communicate the used EPC numbers to Manufacturer M
4. Vendors pre-position EPC numbers of shipped goods at CM
5. At receipt CM reads the 2-vial carton EPCs and the vial EPCs, verifies with Manufacturer M the EPC validity, fills in the vials with active ingredient
6. CM sends to Manufacturer M the vial EPC numbers
7. CM reads the 2-vial carton EPC, verifies with Manufacturer M the EPC validity, assembles 2 vials in a 2-vial carton

8. CM sends to Manufacturer M the 2-vial carton EPC numbers used

Fig. 4.3 - Vial Packaging: Information Flow
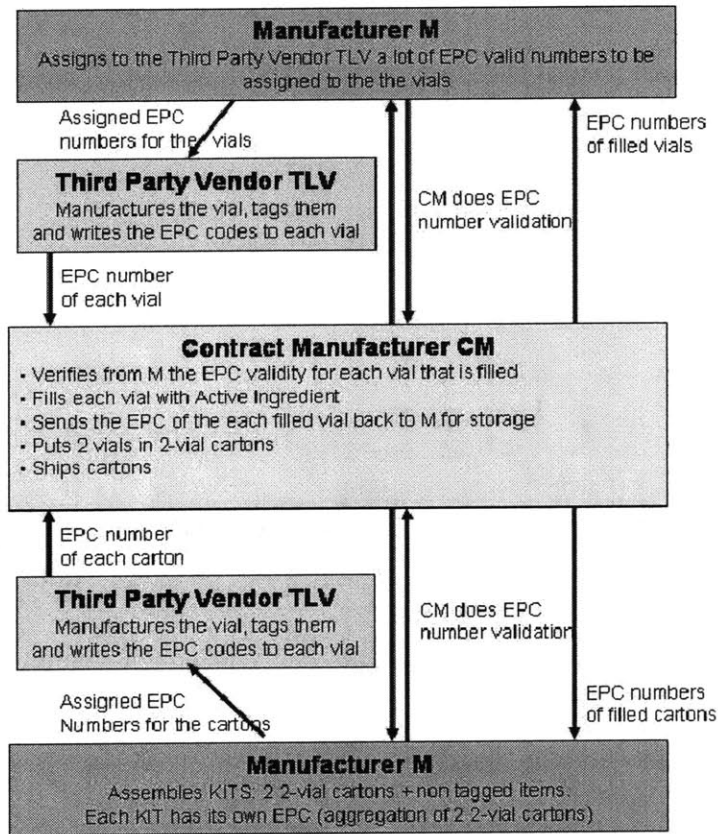
Each vial EPC inherits, at the Contract Manufacturer CM, the aggregated information coming from the Manufacturer M – API. Information from Manufacturer M – API:

- Active ingredient, Lot #, Expiration date, composition, etc.
- Barrel (containing Active Principle) number, type, size, weight, etc.

- Details on the shipment of barrels like, shipment number, documents, carrier type, origin and destination, etc.

The Contract Manufacturer CM will aggregate the 2-vial cartons in boxes and create shipments. The process at the Contract Manufacturer will generate the following aggregated information:

- Vial EPC numbers (each vial EPC inherited the active ingredient information)
- Number of vials
- 2-vial carton EPC numbers
- Number of 2-vial cartons
- Box EPC numbers
- Number, weight and dimensions of boxes
- Pallet EPC numbers
- Number, weight and dimensions of pallets
- Shipment EPC numbers
- Shipment details (origin, destination, documents, etc)

4.6.5 Information flow at Manufacturer M – Assembly

Manufacturer M assembles the KITs of MD01, putting two 2-vial tagged cartons and other non tagged items into a tagged KIT. The KIT box has its own EPC assigned by the manufacturer. Manufacturer M will ship the KITs to the Manufacturer Distribution Center DCM. The process at the Manufacturer M - Assembly will generate the following aggregated information:

- KIT EPC numbers (each KIT EPC inherited the vial and 2-vial carton information)

- Box EPC numbers (KITs are aggregated in bigger boxes)
- Number, weight and dimensions of boxes
- Pallet EPC numbers
- Number, weight and dimensions of pallets
- Shipment EPC numbers
- Shipment details (origin, destination, truck number documents, etc)

4.6.6 Information flow at the Manufacturer Distribution Center DCM

The distribution center DCM stocks the KITs and ships truckloads to the Dispensing Company D. DCM acts as a buffer between Manufacturer M and Dispensing Company D and consolidates KITs into full truckload shipments. The process at the Manufacturer Distribution Center DCM will generate the following aggregated information:

- Box EPC numbers (KITs are aggregated in bigger boxes)
- Number, weight and dimensions of boxes
- Pallet EPC numbers
- Number, weight and dimensions of pallets
- Container EPC numbers (if KITs are shipped in containers)
- Shipment EPC numbers
- Shipment details (origin, destination, documents, etc)

4.6.7 Information flow at the Dispensing Company D

Dispensing Company D is a licensed-pharmacy distribution center. Dispensing Company D is in charge of delivering KITs to the final user, being it a hospital or a patient. Dispensing Company D ships each KIT in a secured shipment, by using special carriers.

Each shipment is done against a doctor's prescription and requires full proof of delivery, i.e., the signature of the recipient.

In our model we will not track the shipment up to the final patient but we will link the shipment data to the KITs that are shipped. This allows the Dispensing Company D to know exactly what vials are in each shipped KIT and to whom the KIT was sent.

The process at the Dispensing Company D will generate the following aggregated information:

- Shipment EPC numbers
- Shipment details (origin, destination, documents, etc)
- Shipment Proof of Delivery (POD)

5   *Conclusion and Future Research Opportunities*

In this thesis we analyzed how the Auto-ID technology and infrastructure could provide full Product Traceability functionality and especially, how full Product Traceability functionality would be possible for the specific supply chain under examination.

In particular the distribution model under study demonstrates how Product Traceability depends on the fundamental Auto-ID concepts of data pre-positioning, aggregation and inheritance.

Moreover, we showed how, for this specific supply chain, the Auto-ID infrastructure would improve the management of drug recalls, returns and shelf life and reduce drug diversions, re-importation, grey markets and counterfeiting.

5.1 Implications of Auto-ID Infrastructure on Product Traceability

5.1.1 Drug Pedigree

As explained in the previous sections, the Auto-ID information infrastructure allows to record and link detailed information about a product, over the full supply chain. PML Servers will provide the functionality for effectively exchanging this information and for effectively performing the aggregation and inheritance processes.

Full drug pedigree requires the most advanced and complete implementation of the Auto-ID infrastructure because a complete drug pedigree would require all the participants to the supply chain to read the EPCs and record them on some PML server.

In such a hypothesis, it would be possible to know exactly where and for how long a drug has been, or how it has moved and how long was the transportation time. Telemetric information as well as GPS information could provide real-time readings of temperature and position.

Particularly important to mention is a proposed law (reported in Appendix I) from the State of Florida on Pedigree Paper Requirements. The law clearly describes the minimum suggested requirements for the drug pedigree. These elements are set forth in Rule 64F-12.012(3), Florida Administrative Code and reported here:

a) Name of the Rx drug (proprietary or generic);
b) Manufacturer of distributor listed on the product label;
c) Dosage form;

d) Strength;

e) Container size;

f) Quantity by lot number;

g) Name and address of each owner of the prescription drug;

h) Name and address of each location from which the drug was shipped if different from the owner's; and

i) The transaction dates.

As previously said, aggregation and inheritance would allow to create such a pedigree and even to bring the process to a step further by linking, for example, a vial of the MD01 product to the active ingredient used to fill in the vial. Auto-ID would make it possible to know what plant produced that active ingredient, at what time of the day, with what raw materials and with what process.

5.1.2 Recalls

Recalling a pharmaceutical product is usually extremely expensive both in terms of direct costs (transportation, lost sales) and indirect costs (marketing necessary to rebuild confidence in the brand). The main problem of recalls is that it is extremely difficult to know where exactly the items to recall are in the supply chain. Is the product still on hand at some distributor or was the product already sold to a patient?

Typically manufacturers recall by lot number however, distributors, pharmacies and hospitals usually don't record the lot number in their ERP or Inventory Management

systems so there is no electronic record in their databases that could be searched by lot number.

Even if all the parties in the supply chain recorded the lot number and it were possible for them to know what is on hand, it would be very hard (with the bar code technology used today) to efficiently find any specific lot in a distribution center or even in a pharmacy in order to recall the products. This kind of search is today only manually and it typically doesn't offer the highest degree of confidence (many items could on hand but could not be found).

Auto-ID infrastructure together with RFID technology would be a clear answer to the problem. First, Auto-ID Product Traceability functionality would allow to find exactly where in the supply chain are all the EPCs corresponding to the specific product and lot number. Second, once the products have been found, the technology infrastructure of RF readers and Savants could exactly identify the locations of all the EPCs to be recalled. Each party in the supply chain would know exactly how many items to recall and where they are located in their warehouses, distribution centers, or pharmacies.

5.1.3 Returns

How can big pharmaceutical distributors verify whether an item that is returned to them was actually sold by them in the first place? Today, they can't, it's just impossible. Without mass serialization, i.e., without the ability to distinguish between two items that are otherwise identical (same product, dosage, packaging, etc) pharmaceutical

distributors and pharmacies do not have the capability to know whether they should accept a return or not because they don't know whether that specific product was sold by them of by a competitor. They will accept any item returned to them, provided that they commonly carry such an item, just to provide good customer service. This has obvious economical implications.

To complicate the issue, the State of Georgia issued a new law that will force pharmaceutical distributors to accept returns of products independently from the minimal unit size. For instance, let's suppose a distributor sells product A only in cases of 10 bottles. In the future, the distributor will be forced to accept a return of less than 10 bottles.

Auto-ID infrastructure would allow to determine if the product was actually sold by the distributor and whether the distributor should be accepted it: Each item would have a full pedigree and so the seller could be identified.

5.1.4 Shelf Life

Effective shelf life management strictly depends on the capability to know exactly what items are on the shelves or on the warehouse racks. Typically pharmaceutical companies, distributors and pharmacies use the FIFO (First In First Out) method of managing inventory. The assumption is that under FIFO the inventory should be always up do date and so none of the items should be expired.

The only actual check of the expiration date happens at the receiving point. Pharmacies usually manually check each item and verify that the expiration date is at least 6 months in the future (otherwise the item will be rejected and sent back to the manufacturer or distributor). The expiration date is typically not recorded by any ERP or warehouse management system.

Auto-ID could radically change the shelf-life management because it would allow to know exactly where the items close to expiring are located:

1. RF readers could constantly monitor the exact inventory on the shelf
2. Each item on the shelf would be uniquely identified by its EPC number
3. Each EPC number would be linked to the expiration date of the item itself [Alexander, 2002]

5.1.5 Diversions/Re-importation and Grey Market

Advanced Product Traceability and full drug pedigree could fundamentally reduce illegal diversions, re-importation and grey markets.

Diversions of Over The Counter pharmaceuticals (OTC) are not illegal in the US and pharmacies typically buy 97% of their OTC product from major pharmaceutical distributors or directly from the manufacturers and buy the remaining 3% from other minor certified distributors (the numbers were given in interviews and so are to be considered only an estimate).

Although diversions for OTC are not illegal, they are a concern from the safety point of view because they could open gates to the introduction of counterfeit, deteriorate or mishandled drugs.

Diversions, grey market and re-importations are some of the major pathways for counterfeit pharmaceuticals to enter the United States and other countries. Diversion has many facets. Some schemes are extremely sophisticated, involving the establishment of phony companies in different countries and elaborate money transfer mechanisms. Other times, stolen product are simply smuggled back to the US or Europe.

Although diversions of goods are technically illegal in the US for prescription pharmaceuticals, the profit of such activity can be huge and make the practice very attractive to unscrupulous operators.

Re-importation is another thorny issue. Several major US pharmaceutical companies are fighting re-importation from Canada to the States because the big price difference for the same product in the two countries (up to ten times) can make the practice of re-importation very profitable.

Re-importations particularly hurt developing countries, where pharmaceutical companies usually sell below the market price. The problem is that very often, a considerable amount of products "disappears" from the developing country and "reappears" in developed countries. This is not hypothetical: In South Africa, almost 50% of the pharmaceuticals entrusted to the Government itself, are stolen [Bureau of Drug Surveillance , 1998; Dahmen, 2002; de Kieffer et al, 2002; de Kieffer et al, 2003].

Because of this, developing countries do not have enough "real" medicines (counterfeit medicines are abundant) and pharmaceutical companies are unwilling to sell the newest most expensive medicines at lower price.

The pedigree functionality, provided by Auto-ID could solve the problem because the pedigree could show in what market the drug was supposed to be sold and could identify when a drug is being sold in the "wrong" market.

5.1.6 Counterfeit Drugs

For a detailed treatment of how Auto-ID could solve the problem of counterfeit drugs the reader should refer to other Auto-ID published literature (A whole thesis has been written on the argument) [Indranil, 2003]. In this thesis we want to point out that full Product Traceability is necessary for identifying counterfeit drugs. By recording the pedigree of a drug, it is possible to know whether the drug had been mishandled, sold to non-certified third parties, or whether the drug is a complete fake.

It happens, for example, that discarded original packages make it back to supply chain by being stolen from hospital dumpsters. Even if, in such a case, the package would have a real EPC number assigned to it by a certified manufacturer, the Auto-ID infrastructure would be able to determine that this old EPC number had been discarded and so it should not reappear in the supply chain.

5.1.7 Patient Safety

Product Traceability will ultimately improve the overall patient safety because it will guarantee better and safer products to the patient and will allow doctors and nurses to deliver better care (see section 1 and Appendix I).

It is important to mention that Auto-ID information infrastructure, by means of the PML server, allows to perform process monitoring [Floerkemeier et al., 2002]. For instance, process monitoring would be extremely valuable in hospital pharmacies, during therapy preparation. We had the chance to visit the Harvard Children Hospital pharmacy and to witness the complexity and the many steps required for some of the intra-venous preparations. Such processes are strictly monitored by experienced pharmacists but none of the steps is recorded in a database. Auto-ID could facilitate the data acquisition at each step so that eventual mistakes could be logged and proactive action could be taken.

Particularly relevant, to understand Patient Safety within hospitals, has been our visit to the San Raffaele Hospital in Milan. San Raffaele managed a EU funded, EURO 4.2M research project called DRIVE, Drugs in Virtual Enterprise [DRIVE, 2003] to demonstrate the ethical, social and industrial paybacks provided by focusing on the integration of the clinical process - which represents the process within the hospital that are directly or indirectly aimed at the patient's health status changes from the admission until discharge -, and the pharmaceutical supply chain - which represents the flow process of the pharmaceutical products, from the manufacturer to the point of use (patient's bedside) -.

DRIVE clearly demonstrated how the integration of clinical process and pharmaceutical supply chain could drastically reduce Adverse Drug Events (ADE) in the administration of medicines to patients and how a controlled supply chain could extend patient safety from the manufacturing plant to the bed side.

5.2   Future Research Opportunities

To conclude our research, we would like to point out that mass serialization and the Auto-ID infrastructure could allow very interesting "revolutionary" applications for the health care industry. We think that the following are areas worth future research:

5.2.1   Applications to designer drugs

The Human Genome Project could create the opportunity for a more focused and personalized drug development [Philipkoski, 2003]. Such drugs will be mainly manufactured "to order" and will be effective only if delivered to the right person or group. Designer drugs will introduce huge complications both in the manufacturing and in the distribution processes and Auto-ID could help in both. Auto-ID could streamline the manufacturing process by linking the EPC of the final patient to a specific manufacturing process so that the process would follow a "recipe" specific for the individual for whom the drug is destined.

Auto-ID could manage the increased complications of the distribution process as well. The need for mass serialization will be particularly strong for this kind of drugs since, potentially, pharmacies and distribution centers will have to handle millions of items that differ from each other because each is engineered for specific individuals.

5.2.2 Hospital automation

The Auto-ID infrastructure could be applied to improve information sharing among hospitals. An EPC could be assigned to an MRI picture and this picture would be available nationally (or worldwide), provided that the proper privacy rules are defined. An MRI picture is an electronic file and, as any other file, it could be handled by a PML server.

The same would be true for patient information. In principle, hospitals could share patient information and, most importantly, patient history, in real time. In the "integrated" hospital, in which patients, medical exams and pharmaceutical products are all identified by their unique EPC, it would be possible to always verify that the right medicine is delivered to the right patient and to check for allergies, interactions among drugs, recalled lots, expiration dates, etc.

Therapy preparation (where many different drugs may be mixed) could be monitored against Auto-ID controlled, pre-defined "recipes" so that errors could be drastically reduced.

5.2.3 Expediting clinical trials

Clinical trials are a very important phase in pharmaceutical research. Clinical trials can last for years and cost millions of dollars so any way to improve the trial process could have a huge impact in reducing time to market of a drug and, ultimately, its price.

We believe that the Auto-ID infrastructure could help in streamlining the data gathering process during clinical trials because it could provide an efficient way to measure and record what drug each participant to the trial took (dosage, placebo, etc) and when. Each pill, vial, etc could be linked to a specific production process.

5.2.4 Improved home care and intelligent cabinet

One hundred million Americans live with chronic illnesses [Bodenheimer, 1999] yet physicians are not adequately caring for this population. Fewer than 25% of patients with hypertension have a well controlled blood pressure [Stockwell, 1994], 20% of patients with Type I diabetes see a physician less than once a year and 41% do not have annual retinal examinations [Anderson, 1996]. Many primary care physicians are preoccupied with acute disorders and do not have organized systems tailored to less urgent problems [Wagner, 1996]. In addition to that, surveys by pharmaceutical companies suggest that, for instance, only 45 to 75% of diabetics take their medications regularly [Adomeit, 2001]. Physicians have no systems in place for monitoring that and providing efficient care at patient's home.

Auto-ID technology and infrastructure could improve patient care at home by providing "smart cabinets" that could detect whether a patient is taking or not the proper medicine at the proper time, could monitor interactions among different drugs in the cabinet and could provide useful information and direct feedback/alerts to the primary physician.

5.2.5 *Effectiveness of drug in real market*

Clinical trials measure the efficacy of a drug but the actual worldwide utilization of the drug by millions of people gives indication of the actual effectiveness of the drug. Measuring and recording the effectiveness of a drug is a complicated issue, but mass serialization and the Auto-ID infrastructure could help by simplifying the process by facilitating data acquisition and patient's feedback through, for example, wireless technology (like PDA's) and allowing the identification of drug and patient within chain. Information would be ubiquitous over the Auto-ID PML server network and algorithms could be run on the data in order to detect behavioral paths (for example counter effects), within the patient population.

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70

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Appendix I: American and European Legislation on Patient Safety

American Legislation

H.R.663 Patient Safety and Quality Improvement Act – Section 5

On February 11, 2003, the H.R. 663 bill was introduced in the House or Representatives to amend "title IX" of the Public Health Service Act to provide for the improvement of patient safety and to reduce the incidence of events that adversely affect patient safety, and for other purposes.

SEC. 5. REQUIRED USE OF PRODUCT IDENTIFICATION TECHNOLOGY.

The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended--

(1) in section 502, by adding at the end the following:

> (w) If it is a drug or biological product, unless it includes a unique product
>
> identifier for the drug or biological product as required by regulations under
>
> section 510(q).'; and

(2) in section 510, b

(1) The Secretary shall issue, and may periodically revise, regulations requiring the manufacturer of any drug or biological product that is subject to regulation by the Food and Drug Administration, or the packager or labeler of a drug or biological product that is

subject to regulation by the Food and Drug Administration, to include a unique product identifier on the packaging of the drug or biological product.

(2) For purposes of this subsection, the term `unique product identifier' means an identification that--

> (A) is affixed by the manufacturer, labeler, or packager to each drug or biological product described in paragraph (1) at each packaging level;

> (B) uniquely identifies the item and meets the standards required by this section; and

> (C) can be read by a scanning device or other technology acceptable to the Secretary.

(3) A unique product identifier required by regulations issued or revised under paragraph (1) shall be based on--

> (A) the National Drug Code maintained by the Food and Drug Administration;

> (B) commercially accepted standards established by organizations that are accredited by the American National Standards Institute, such as the Health Industry Business Communication Council or the Uniform Code Council; or

> (C) other identification formats that the Secretary deems appropriate.

(4) The Secretary may, at the Secretary's discretion, waive the requirements of this section, or add additional provisions that are necessary to safeguard the public health.

California Senate Bill 1875, 28 September 2000

(6 February 2002)

http://www.leginfo.ca.gov/bilinfo.html

BILL NUMBER: SB 1875 CHAPTERED

BILL TEXT
CHAPTER 816
FILED WITH SECRETARY OF STATE   SEPTEMBER 28, 2000
APPROVED BY GOVERNOR   SEPTEMBER 28, 2000
PASSED THE SENATE   AUGUST 31, 2000
PASSED THE ASSEMBLY   AUGUST 30, 2000
AMENDED IN ASSEMBLY   AUGUST 29, 2000
AMENDED IN ASSEMBLY   AUGUST 25, 2000
AMENDED IN ASSEMBLY   AUGUST 18, 2000
AMENDED IN ASSEMBLY   AUGUST 7, 2000
AMENDED IN SENATE   MAY 16, 2000
AMENDED IN SENATE   APRIL 25, 2000
AMENDED IN SENATE   APRIL 6, 2000

INTRODUCED BY Senator Speier

FEBRUARY 24, 2000

An act to add Chapter 2.05 (commencing with Section 1339.63) to Division 2 of the Health and Safety Code, relating to health.

LEGISLATIVE COUNSEL'S DIGEST

SB 1875, Speier. Health facilities and clinics: medication-related errors.

Existing law generally regulates the licensure of health facilities and clinics, as defined, and prescribes the duties of the State Department of Health Services in this regard. Under existing law, any person who violates provisions regulating health facilities, or who willfully or repeatedly violates any rule or regulation adopted thereunder is guilty of a misdemeanor. This bill would make it a condition of licensure that these facilities, with certain exceptions, implement a formal plan, on or before January 1, 2005, to eliminate or substantially reduce medication-related errors in the facility. Since a violation of the provisions applicable to health facilities is a crime, the bill would impose

a state-mandated local program. The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement. This bill would provide that no reimbursement is required by this act for a specified reason. THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Chapter 2.05 (commencing with Section 1339.63) is added to Division 2 of the Health and Safety Code, to read:

CHAPTER 2.05. MINIMIZATION OF MEDICATION-RELATED ERRORS

1339.63. (a) (1) As a condition of licensure under this division, every general acute care hospital, as defined in subdivision (a) of Section 1250, special hospital, as defined in subdivision (f) of Section 1250, and surgical clinic, as defined in paragraph (1) of subdivision (b) of Section 1204, *shall adopt a formal plan to eliminate or substantially reduce medication-related errors.* With the exception of small and rural hospitals, as defined in Section 124840, *this plan shall include technology implementation, such as, but not limited to, computerized physician order entry or other technology that, based upon independent, expert scientific advice and data, has been shown effective in eliminating or substantially reducing medication-related errors.*

(2) Each facility's plan shall be provided to the State Department of Health Services no later than January 1, 2002. Within 90 days after submitting a plan, the department shall either approve the plan, or return it to the facility with comments and suggestions for improvement. The facility shall revise and resubmit the plan within 90 days after receiving it from the department. The department shall provide final written approval

within 90 days after resubmission, but in no event later than January 1, 2003. ***The plan shall be implemented on or before January 1, 2005.***

(b) Any of the following facilities that is in the process of constructing a new structure or retrofitting an existing structure for the purposes of complying with seismic safety requirements shall be exempt from implementing a plan by January 1, 2005:

(1) General acute care hospitals, as defined in subdivision (a) of Section 1250.

(2) Special hospitals, as defined in subdivision (f) of Section 1250.

(3) Surgical clinics, as defined in paragraph (1) of subdivision

(b) of Section 1204.

(c) The implementation date for facilities that are in the process of constructing a new structure or retrofitting an existing structure shall be six months after the date of completion of all retrofitting or new construction. The exemption and new implementation date specified in this paragraph shall apply to those facilities that have construction plans and financing for these projects in place no later than July 1, 2002.

(d) For purposes of this chapter, a "medication-related error" means any preventable medication-related event that adversely affects a patient in a facility listed in subdivision (a), and that is related to professional practice, or health care products, procedures, and systems, including, but not limited to, prescribing, prescription order communications, product labeling, packaging and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIIIB of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or

infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIIIB of the California Constitution.

FDA Proposes Drug Bar Code Regulation

http://www.fda.gov/oc/initiatives/barcode-sadr/fs-barcode.html

March 12, 2003

Today's Action

In an effort to improve patient safety in the hospital setting by reducing medication errors, the Food and Drug Administration (FDA) has published a proposed rule titled, **Bar Code Label Requirements for Human Drug Products and Blood.**

Proposed Rule--

FDA is proposing a new regulation that would require "bar codes" on all prescription, some over-the-counter drugs and vaccines. Bar codes are symbols consisting of horizontal lines and spaces and are commonly seen on most consumer goods. In retail settings, bar codes identify the specific product and allow software to link the product to price and other sales- and inventory-related information. FDA's bar code rule would use bar codes to address an important public health concern - medication errors associated with drug products.

How Would It Work --

FDA's regulation proposes to require bar codes on prescription drugs, over-the-counter drugs packaged for hospital use, and vaccines. The bar code would, at a minimum, contain the drug's National Drug Code number, which uniquely identifies the drug, its strength, and its dosage form (e.g., 10 mg. capsule). FDA seeks comment on whether to add information such as lot number and expiration date. The proposed rule would also cover blood and blood components.

- The bar code, when used in conjunction with a bar code scanning system and computerized database, would work as follows:
- A patient is admitted to the hospital. The hospital gives the patient a bar-coded identification bracelet to link the patient to his or her computerized medical record.
- As outlined in this proposal, every prescription drug and certain over-the-counter drugs would have a bar code on its label. The bar code would reflect the drug's National Drug Code number.
- The hospital would have a bar code scanners or readers that are linked to the hospital's computer system of electronic medical records.
- Before a healthcare worker administers a drug to the patient, the healthcare worker scans the patient's bar code. This allows the computer to pull up the patient's computerized medical record.
- The healthcare worker then scans the drug(s) that the hospital pharmacy has provided to be administered to the patient. This scan informs the computer which drug is being administered.
- The computer then compares the patient's medical record to the drug(s) being administered to ensure that they match what is prescribed for the patient.
- If there is a problem, the computer sends an error message, and the healthcare worker investigates the problem.
- The problem could be one of many things:
  o Wrong dose of drug
  o Wrong drug

80

- o Wrong time to administer the drug
- o The patient's chart has been updated and the prescribed medication has changed

So, for example, a child would not receive an adult dosage of a drug when bar coding was employed, nor would a patient mistakenly receive a duplicate dose of a drug they had already received. A bar code system could also allow the computer to record the time that the patient receives the drug, ensuring more accurate medical records.

Improving Patient Safety:

The Institute of Medicine and other expert bodies have concluded that medical errors have substantial costs in lives, injuries, and wasted health care resources, and that misuse of drugs is a major component of those errors.

FDA estimates that the bar code rule, once implemented, will result in a 50% increase in the interception of medication errors at the "dispensing and administration" stages. This will result in 413,000 fewer adverse events over the next 20 years. Some hospitals that currently have bar code systems in place report even greater reductions in errors from bar code usage. Bar codes may also help prevent other types of medication errors, such as in prescribing and transcribing, because they will encourage health care organizations to adopt computerized systems for handling prescriptions.

Additionally, the adoption of bar codes for hospital patient care may promote their use in other hospital and non-hospital settings.

Other Benefits:

Patients would avoid pain, suffering, and extensions of hospital stays with an estimated present value of $41 billion over those 20 years. For example, in a study at a Veterans Affairs Medical Center[1] that employed a bar code scanning medication dispensing system, 5.7 million doses of medication were administered to patients with no medication errors when the technology was used as designed. In addition, hospitals are expected to avoid litigation associated with preventable adverse events, reduce malpractice liability insurance premiums, and increase receipts from more accurate billing procedures.

Other parties may also benefit from bar codes on drugs. For example:

Bar codes could make it easier for hospitals and other health care facilities to enter medication order entries into a patient's electronic medical records, help in inventory control and billing, and conserve hospital or healthcare staff resources or free those resources so that they can be devoted to patient care. Hospitals would no longer have to go through the costly process of generating their own bar codes and repackaging drugs, or to worry about different electronic standards from different manufacturers. A hospital association stated that standardized, universal bar codes could also improve patient care and safety, increase workforce productivity and satisfaction, streamline administrative systems, lead to efficient management of assets and resources, and meet consumer expectations for service and access to information. For all of these reasons, FDA's bar coding standards are likely to accelerate the adoption of safety-improving information technologies by hospitals and nursing homes.

In the retail setting, pharmacists could use the bar codes, in conjunction with computerized prescription orders, to confirm that the right drug is being dispensed to the right patient. Pharmacies will benefit from standard codes that will be used by all prescription manufacturers.

Drug manufacturers will benefit from uniform standards, rather than having to worry about conflicting requirements from different purchasers that would add to the cost of adopting bar coding. It is likely that, once the FDA standards are finalized, many manufacturers may quickly begin incorporating the bar codes on their products - even before the rule takes effect.

Industry groups have said that the installation of scanning systems may lead to more efficient purchasing and supply utilization and other potential risk management activities.

[1] Ref. (1) Malcolm, B., Carlson, R.A., Tucker, C.L. and Willette, C., "Veterans Affairs: Eliminating Medication Errors Through Point-of-Care Devices," Technical Paper for 2000 Annual HIMSS Conference, (November 30, 1999).

Florida Law: Pedigree Paper Requirements
http://www.doh.state.fl.us/pharmacy/drugs/pedigree.htm

November 2001

Attention: Regulatory Affairs

This communication provides the bureau's responses to various inquiries we've received on the Pedigree Paper requirements. We thought sharing this information with all

prescription drug wholesalers would be beneficial to help assure compliance with this requirement. Footnotes at the end of the document provide the specific statutory and rule language referenced in the responses.

1. *What do you mean by pedigree papers?*

A pedigree paper is the written history identifying each of the previous sales of a prescription (Rx) drug[3].

2. *I buy most of my Rx drugs directly from the manufacturer. The manufacturer recognizes me as an authorized distributor of record. Do I have to provide pedigree papers?*

For the specific Rx drug bottle or container you purchase directly from the manufacturer as an authorized distributor of record, you do not have to provide a pedigree paper. However, if you purchase any Rx drug bottle or container from anyone other than the manufacturer, then you need to provide a pedigree paper for all the Rx drug bottles or containers that were not purchased directly from the manufacturer.

3. *What or who is an authorized distributor of record?*

Florida law defines "authorized distributors of record" as those distributors with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's products. Florida's rules further define "ongoing relationship" to mean an association that exists when a manufacturer and a distributor enter into a written agreement under which the distributor is authorized to distribute the manufacturer's product(s) for a period of time or for a number of shipments, at least one sale is made under that agreement, and the name of the authorized distributor of record is entered on the manufacturer's list of

authorized distributors of record or equivalent list. An ongoing relationship may also be documented by at least three purchases of a manufacturer's product(s) directly from that manufacturer within a six month period from the date for which the authorized distributor of record relationship is claimed and the distributor's name is entered on the manufacturer's list of authorized distributors of record or equivalent list.

4. *Do I have to provide a pedigree paper to my pharmacy customers?*

Under Florida law, no, you only need to provide a pedigree paper to customers that are wholesale distributors. However, the federal law[1] states that if a pedigree paper is required, it must be provided to each recipient of the Rx drug. This includes pharmacy customers.

5. *The federal rules have not been finalized yet. Can I wait until those rules are final before I begin providing pedigree papers?*

No. Florida Statutes have required pedigree papers since 1993. The rule that outlines the elements required on a pedigree paper for a wholesaler doing business in or into Florida became effective in July, 1996. Although others may be affected, if you receive this communiqué, you should be providing pedigree papers whenever required.

6. *What information must be included on a pedigree paper?*

a) name of the Rx drug (proprietary or generic);

b) manufacturer of distributor listed on the product label;

c) dosage form;

d) strength;

e) container size;

f) quantity by lot number;

g) name and address of each owner of the prescription drug;

h) name and address of each location from which the drug was shipped if different from the owner's; and

i) the transaction dates.

These elements are set forth in Rule 64F-12.012(3), Florida Administrative Code.[2]

7. *Does the pedigree paper have to trace the Rx drug all the way back to the manufacturer or just to the authorized distributor of record?*

Florida's law requires the pedigree paper to trace the drug all the way back to the manufacturer. The Florida language states that the written statement must identify "each previous sale of the drug." Additionally, the next sentence begins, "The written statement identifying all sales..." Although the federal rule has not be become effective yet, it appears that the federal rule may not require tracing the product back to the manufacturer. However, in the regulatory scheme for prescription drugs, a state may have a more stringent requirement than the federal requirements. The state statute referred to here is s. 499.0121(6)(d), F.S.[3]

8. *What am I supposed to do if my vendor-supplier won't or doesn't give me a pedigree paper?*

Florida's law requires the pedigree paper to be provided before the transaction. This requirement is in place so the wholesaler that is purchasing the Rx drug can fully examine the product to prevent acceptance of prescription drugs that are unfit for distribution or use[4]. A thorough review of the entire pedigree paper can assist in this assessment. Therefore, if the vendor-supplier does not provide a pedigree paper and is not

an authorized distributor of record, or provides one that raises questions as to the integrity of the product, you may wish to decline the purchase of those Rx drugs because the purchase may be in violation of Chapter 499, F.S.

9. *What do I need to do if the vendor-supplier does not give me a pedigree paper because the vendor-supplier claims to be an authorized distributor of record?*
You can contact the manufacturer to ascertain whether the vendor-supplier is listed by the manufacturer as an authorized distributor of record. You may want to request the manufacturer to fax you a copy of the list or make a note in the file as to the date, time, telephone number, and name of the person you spoke with at the manufacturer's facility that confirmed the vendor-supplier is an authorized distributor of record for the product.

10. *Do I have to keep a copy of the pedigree papers I receive?*
Yes. Rule 64F-12.012(3), Florida Administrative Code requires you to keep a copy.

11. *Do I have to keep a copy of the pedigree paper I provide?*
It is a good idea to keep a copy of the pedigree papers that you provided to a customer to document that you did comply with the requirement.

12. *What are the penalties for pedigree paper deficiencies?*
Deficiencies in pedigree papers may violate at least three prohibited acts. These include the failure to maintain records required by chapter 499 and the rules (s. 499.005(18), F.S.); providing the department with false or fraudulent records or making false or fraudulent statements regarding any matter within the provisions of chapter 499 (s. 499.005(19), F.S.); and engaging in misrepresentation or fraud in the distribution of a drug (s. 499.005(23), F.S.). Violations of these provisions may subject you or your firm

to criminal prosecution; administrative fines ranging from $250 - $5,000 per violation per day; suspension or revocation of the prescription drug wholesaler permit; or a combination of these penalties depending on the severity of the deficiency.

The Bureau of Pharmacy Services will be looking more closely at your compliance with the pedigree paper requirements under the Florida Drug and Cosmetic Act, Chapter 499, Florida Statutes. We have already initiated action to revoke prescription drug wholesaler permits or impose administrative penalties in cases where pedigree papers were at issue. I encourage you to assure your record keeping procedures for prescription drug wholesaling activities fully address these requirements.

Sincerely,

Sandra R. Stovall

Compliance Officer

sandra_stovall@doh.state.fl.us

[1] Federal law Sec. 503(e)(1)(A) Each person who is engaged in the wholesale distribution of a drug subject to subsection (b) and who is not the manufacturer or an authorized distributor of record of such drug shall, before each wholesale distribution of such drug (including distribution to an authorized distributor of record or to a retail pharmacy), provide to the person who receives the drug a statement (in such form and containing such information as the Secretary may require) identifying each prior sale, purchase, or trade of such drug (including the date of the transaction and the names and addresses of all parties to each transaction).

[2] 64F-12.012(3), Fla. Admin. Code. The pedigree papers required by s. 499.0121(6)(d) must include either the proprietary name or the generic name with the name of the manufacturer or distributor reflected on the label of the product, dosage form, strength,

container size, quantity by lot number, the name and address of each owner of the prescription drug, the name and address of each location from which it was shipped if different from the owner's, and the transaction dates. A copy of the pedigree paper must be maintained by each recipient.

[3] 499.0121(6)(d)1., F.S. Each person who is engaged in the wholesale distribution of a prescription drug, and who is not an authorized distributor of record of such drug, must provide to each wholesale distributor of such drug, before the sale is made to such wholesale distributor, a written statement identifying each previous sale of the drug. The written statement identifying all sales of such drug must accompany the drug for each subsequent wholesale distribution of the drug to a wholesale distributor. The department shall adopt rules relating to the requirements of this written statement.

European Legislation on Patient Safety

With the Law No 388, 23 (December 2000), the Italian Government is enforcing the traceability of each single bottle, vial, blister and strip of medicine by uniquely numbering each item (by using the so called BOLLINI) and it is forcing all the parties in the supply chain to record and archive each single number. The applicability of the law has been delayed several times, until June 2004, due to the lack of a technology suitable for the task. Since January 2002 pharmaceutical manufacturers are applying the uniquely numbered BOLLINI, special bar code labels produced by the Italian Mint, to each item but the actual full traceability will start only in June 2004. A full description of the structure of the database that will supposedly store all the tracing information has not been disclosed to date, but it appears that the Italian Government is oriented to establish a Government managed centralized database for the purpose.

Legge 23 dicembre 2000, n. 388 (BOLLINI LAW)

"Disposizioni per la formazione del bilancio annuale e pluriennale dello Stato (legge finanziaria 2001)"

(Pubblicata nel Supplemento Ordinario n. 302 alla Gazzetta Ufficiale 29 dicembre 2000, n. 302)

Capo I

DISPOSIZIONI DI CARATTERE FINANZIARIO

(omissis)

Capo II

DISPOSIZIONI PER LA RIDUZIONE DEL CARICO FISCALE DELLE FAMIGLIE

Art. 85.

(Riduzione dei ticket e disposizioni in materia di spesa farmaceutica)

[...]

14. Il Ministro della sanità stabilisce, con proprio decreto, i requisiti tecnici e le modalità per l'adozione, entro il 31 marzo 2001, della numerazione progressiva, per singola confezione, dei bollini autoadesivi a lettura automatica dei medicinali prescrivibili nell'ambito del Servizio sanitario nazionale di cui al decreto del Ministro della sanità 29 febbraio 1988, pubblicato nella *Gazzetta Ufficiale* n. 79 del 5 aprile 1988, e successive modificazioni. A decorrere dal sesto mese successivo alla data di pubblicazione del decreto di cui al precedente periodo, le confezioni dei medicinali erogabili dal Servizio sanitario nazionale devono essere dotate di bollini conformi alle prescrizioni del predetto decreto. Con la stessa decorrenza, i produttori, i depositari ed i grossisti mantengono memoria nei propri archivi del numero identificativo di ciascuno dei pezzi usciti e della destinazione di questi; i depositari, i grossisti ed i farmacisti mantengono memoria nei

propri archivi del numero identificativo di ciascuno dei pezzi entrati e della provenienza di questi. La mancata o non corretta archiviazione dei dati comporta l'applicazione della sanzione amministrativa pecuniaria da lire 3 milioni a lire 18 milioni.

Appendix II: Product Traceability technology providers

We want to give an overview of various proposed solutions for product traceability, some of which are Government-sponsored projects, some of which are commercial technologies based on RFID technology, barcode or else. This overview is updated as June 2003 and does not pretend to be exhaustive in any way.

Governmental Projects

EU-Project "PROMISE" – Lausanne

ICP: S.EN.S - Swiss Foundation for Waste Management

http://www.ims.org/projects/project_info/promise.html

The purpose of the PROMISE (Product Embedded Information System for Service and End-Of-Life) is to generate a new system for handling lifecycle information. This system will be developed and installed at the participating industrial partners. The industry partners will be able to develop more sustainable products and enhance their business opportunities using the PROMISE technology.

A product system's life cycle is characterized by the following four phases: Design, Production, Use-Service-Maintenance or MOL (Middle-of-Life) and Retirement or, as most commonly is called, EOL (End-of-Life). The retirement or EOL phase is characterized by different scenarios such as: reuse of the whole product with re-furbishing, reuse of components with disassembly and refurbishing, material reclamation without disassembly, material reclamation with disassembly, incineration with energy

recuperation, incineration without energy recuperation and, finally, disposal. All of the above life cycle phases are inter-connected within a system with two types of flows: (i) a material flow and (ii) an information flow.

The PROMISE proposal concerns the information flow of a product system and focuses on the last two phases of the product's life cycle, the Use, Service & Maintenance or MOL and the Retirement or EOL.

TRACAR - c & Cargo Supervision System:

http://www.cordis.lu/telematics/tap_transport/research/projects/tracar.html

European Project: The TRACAR project automated aspects of tracking, tracing and monitoring from end-to-end of the transport supply chain.

From the CORDIS Web Page (European Union): "This web site presents the background, justification and impressive results from the European Union supported transport projects in the Telematics Applications Programme (1994-1998). The achievements of the projects continue the process of developing and harnessing technology to improve European society and competitiveness.

The programme results reinforce the European Union strategy of developing the Information Society. Creating the User-Friendly Information Society is a key policy aim for the European Union. Industrial competitiveness, employment, quality of life and sustainable growth all depend on Europe being at the cutting edge in exploiting Information Society Technologies (IST).

The IST Programme of the EU builds on a decade of Research and Technological

Development (RTD) work and on European policy in liberalising the telecommunications

equipment, services and infrastructure markets. It is highly relevant to transport, travel

and tourism, because it develops intelligent infrastructure and vehicle systems for

efficient mobility management, for increased safety and for the delivery of information

based value-added services."

Ubiquitous ID Center (in JAPANESE):

http://www.uidcenter.org/.

This Center is developing a concept very to Auto-ID's and is trying to gain some traction

among Japanese companies.

Conclusion: Not enough available information. The Ubiquitous ID Center still needs to

catalyze attention on its technology and is still far away from creating a community

buying into the concept.

The TRON Project

http://tronweb.super-nova.co.jp/autoidvubiqid.html

From the TRON Web Site: "Long under research and development by the TRON Project,

Prof. Sakamura announced that a newly established Ubiquitous ID Center would be

giving identification numbers to everything under the sun, both tangible and intangible

items."

Hospital Applications - Automated Medication Dispensing

Pyxis – Barcode based products

http://www.pyxis.com/

From Pyxis Web Site: "Hospitals and other health care providers are continually seeking ways to improve patient safety. Pyxis has created a SAFETYnet of products, services, training and education to respond to this need. With Pyxis, health care professionals can access a range of safe and effective tools to help deliver more efficient and enhanced patient care. Pyxis automation technology and software work together to improve the flow of information, medication and supplies, delivering a total management solution from the wholesaler to the patient's bedside."

Omnicell

http://www.omnicell.com/

From Omnicell Web Site: "Established in 1992, Omnicell is the leading provider of patient safety solutions for healthcare. Addressing the medication-use process and the medical-surgical supply chain, Omnicell's broad range of solutions are used throughout the healthcare facility--in the pharmacy, nursing units, operating room, cardiac cath lab, and all the way to the patient s bedside. Improving patient care by enhancing operational efficiency, Omnicell s solutions include systems for physician order management, automated pharmacy retrieval, medication and supply dispensing, nursing workflow automation at the bedside, and Web-based procurement. These solutions enable

healthcare facilities to reduce medication errors, operate more efficiently, and decrease costs--ultimately contributing to improved clinical and financial outcomes."

Commercial solutions for product traceability

Flying Null

http://www.flying-null.com/

From Flying Null Web Site: "Flying Null developed a unique and innovative system for providing brand protection throughout the product lifecycle. FN tags can give each product an individual identity enabling covert brand protection, through authentication, tracking and tracing. Flying Null technology is a new magnetic sensing technology which can determine remotely the precise position in space of magnetic material. This unique attribute does not require optical line of sight or contact with the tag. FN has many of the benefits of simple RFID, but typically at a fraction of the cost. The size of the thin-film tags and their resistance to heat and pressure, allows embedding into virtually any product and packaging during manufacturing."

ESG – RFID System Integrator

http://www.esg.de/en/services/consulting/RFID-system-integrator/index.html

ESG offers ATT™ - Advanced Tracking & Tracing for items, containers and other logistics entities.

JAMA – Product Tracking and Tracing, The Netherlands

http://www.jadap-matronics.nl/en/systems/ident.htm

Jama B.V. produces radio frequency (RF) identification systems for the use in product tracking & tracing.

Westmont Omron RFID, UK

http://www.westmont.co.uk/main/omrfid.htm

Omron's DeviceNet RFID Controller provides built-in DeviceNet network connectivity for a wide variety of electronic data tracking applications. The controller is fully compatible with a wide variety of Omron's V600 series read/write heads as well as Omron's complete line of passive read/write RFID tags.

Alexandra Associated (RFID-Metal contact):

http://www.trackandtraceit.com/tatit.cfm

Nail transponders can be inserted securely in objects and are particularly useful for security applications. Until recently, applications in and on metal were never really being considered. For more than a year now, SOKYMAT and their Japanese partner Haneda Humepipe Co. Ltd have been in co-operation and succeeded in eliminating this barrier.

Intensecomp

http://www.intensecomp.com/prod_rfid.html

- Document Track and Trace

- Personnel Track and Trace
- Asset Track and Trace

SAVI Technologies

http://www.savi.com/

From the SAVI Web Site: "Savi is the proven leader in global supply chain security and asset management. The Savi SmartChain™ suite of asset management, security and collaboration software applications is uniquely integrated with automatic data collection and identification systems to provide real-time logistics management solutions. Savi Technology works with leading freight transportation carriers, shippers, service providers and owners of supply chain assets to create unique solutions that ensure vastly superior management, visibility, and security of shipments."

Tagsys

http://www.tagsys.net/

TAGSYS designs products and systems to identify and track everyday objects using radio frequency identification technology (RFID).

Proxximity Systems

http://www.solenthub.co.uk/pages/proxximitysystemsportsmouth.html

Proxximity Systems is engaged in the development of medical administration systems specifically concerned with tracking and tagging pathology samples. For example, the NHS processes around 150 million blood samples every year and much of the

administration associated with this is still manual. Doctors, nurses and phlebotomists write patient and other details on paper labels attached to the samples, and a huge amount of data entry has to be done before the actual requested tests are carried out. Once all of this labor intensive work is completed, the tests are carried out in seconds by computer systems linked to automated testing machines.

Master of Branding

http://www.mastersofbranding.com/

Masters Of Branding, in conjunction with several notable corporations and institutions, offers clients a wide range of Radio Frequency Identification solutions

CCL Industries (packaging):

http://www.cclind.com/index_corporate.html

Smart packaging: RFID embedded in labels and packages.

Microtrace, LLC (Product Diversion Identification and Tracing)

http://www.microtaggant.com/successes.htm

The MICROTAGGANT® Identification Particle is essentially a unique numeric code sequence, in multiple colored layer format, to which meaning is assigned. The code particle is highly versatile in its use and application. MICROTAGGANTs have been used in areas of industry, government agencies, law enforcement, and others for over 15 years to provide positive identification and authentication. MICROTAGGANTs are currently being used to identify, authenticate and trace a variety of items. Some of the

MICROTRACE customers have a single unique code sequence for simple yes/no authentication capabilities while others have hundreds of unique code sequences to allow for further identification capabilities.

MICROTAGGANT Applications:

- Added directly to products to prove authenticity for warranty liability issues.
- Used to control unauthorized production of products by controlling the supply of authenticated components
- Applied with clear spray application to the exterior of packaging to identify distributor in product diversion cases
- Incorporated into holograms and tickets for authentication
- Incorporated into drivers licenses and passports for authenticity

Lab-id

http://www.lab-id.com/

Lab-id is a manufacturer of labels, tags and readers. Lab-id is owned by Mauro Benetton and is working with United Colors of Benetton and with Merloni Elettrodomestici on smart appliances. From Merloni Web Site: "The Ariston revolution: thanks to a microchip, washing machines will be able to identify items and decide how to wash them and fridges will tell us the best-before dates of our food"

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