Information Management and Tracking of Drugs in Supply Chains within the Pharmaceutical Industry

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Abstract

The authors examine information management and tracking of drugs in supply chains within the pharmaceutical industry. The focal concern in this setting is counterfeit drugs, a dilemma of paramount importance for public health and the well-being and safety of patients. The authors advocate RFID and related technologies, including EPCglobal’s Electronic Product Code Information Services (EPCIS) and IBM’s RFID Information Center system that, in turn, provide a suitable infrastructure for the tracking and tracing of uniquely identifiable, i.e. mass-serialized, products throughout the supply chain. A two-pronged theoretical framework is presented utilizing Transaction Cost Theory and Collective Action Theory to view the present research setting. Several regulatory efforts and compliance regimes are presented and a call for collective action for all stakeholders within the supply chain in the pharmaceutical industry is advanced.

Key Words: Drug Safety, Pharmaceutical Industry, Tracking, Radio Frequency Identification, RFID, Supply Chain Management

Introduction

Information management (IM) as a field of study is applicable to and encompasses any form of organization. The pharmaceutical industry (PI), the setting of this paper, is no exception. Since the PI is an information-intensive industry, proper management of information is of paramount importance in determining the identity and authenticity of drugs and their ingredients. For all involved, drug safety is often taken for granted when visiting the pharmacy to purchase medicine that cures our various ills. However, the problem of counterfeit drugs and drug ingredients has made its way into the U.S. drug supply chain at alarming and ever increasing rates. Here we outline drug counterfeit IM-related issues in the PI, and how they can be, at least partially, addressed by embracing radio frequency identification (RFID) and related technologies together with a proposed regulatory scheme addressing this dilemma.

The authors provide a case for utilizing RFID technology, along with some process changes, in the PI to help combat drug counterfeiting. This research is supported by data retrieved from multiple sources, including the Food and Drug Administration (FDA), World Health Organization (WHO), and news sources such as the Wall Street Journal and the New York Times. These sources provide a plethora of supporting data helping to illustrate improvements in identity management and authentication polices that could help prevent counterfeit drugs from being sold to patients. And, they show how RFID and an associated infrastructure can be used to track counterfeit drugs from the manufacturer to the store level. This paper focuses on IM issues, identity management and verifying the authenticity of pharmaceutical products, as well as the use of RFID as a means to reduce or control the distribution of counterfeit pharmaceutical products.

The paper is organized as follows: first we provide a brief overview of how identity management and authenticity are central components of information management. This is followed by a brief discussion of RFID and related technologies such as the Electronic Product Code Information Services (EPCIS) infrastructure and how these technologies lend themselves well for assisting with the management of identity and authenticity of products, and especially for tracking and tracing products. Next we present a short perspective on how our research is viewed on theoretical and conceptual grounds by using Transaction Cost Theory and Collective Action Theory. We then provide reviews on the central topic of our paper. Finally, our paper offers concluding thoughts.

Information Management: Identity Management and Authentication

Identity management is simply a tool to help identify a person, place, or thing [1]. It can be used within multiple areas, including technology and security. Confirming the identity of a person is a common event, such as showing an ID when attempting to cash a check at the bank. For many products identities are not as essential. For example, the manufacturer of nails does not necessarily care where the metal comes from. But, the beef industry needs to know the origin of each cow in case there is an outbreak of disease so the source can be located. These examples show how identity management can come in multiple forms, but its importance depends on the field or industry in which it is utilized.

Along with identity management, authentication is a
means of confirming something or someone to be authentic [1]. It can also confirm the identity of a person or tracing the path of an item back to its origin. To authenticate an item, its attributes are compared with known characteristics of its creator. For example, a painting from Picasso can be authenticated by art experts by examining the attributes of the work. If they match known patterns, such as style and time of creation, then the painting can be called authentic. Following, we discuss technology that can be utilized to assist with identity management and authentication.

**RFID, EPCIS and a RFID-Based Infrastructure**

Before addressing counterfeiting in the PI and related IM issues, a brief introduction to radio frequency identification (RFID) is in order. First, RFID is not a new technology. It was developed in World War II as a means of identifying friendly airplanes from enemy airplanes using radar over a battlefield [2]. More recently, RFID has been adopted for use by supply chain management by retail giants such as Walmart. A product can be tagged with a RFID chip at the manufacturer. Products are typically tagged chips at the palette, case and individual product item levels. This tag may allow the purchaser of the product to ensure its identity and validity once it arrives at its destination.

RFID tags work by one of two methods – active or passive. Active tags have a battery, while passive tags do not. Passive tags get their power from an interrogator. It generates an electro-magnetic field providing sufficient power to transmit and read the recorded information on the tag, i.e. RFID chip. Due to higher costs of an active tag, passive tags currently dominate the market. Almost any information may be recorded on these tags, including serial numbers, product IDs, etc. These serial numbers make it possible to verify a product’s identity and authenticity, date of manufacture, etc. Such information could potentially save lives (as with certain pharmaceutical products) as products move through supply chains and are distributed. The creation, adoption, and standardization of RFID products by companies have come about relatively slowly, but increasingly yet deliberately companies are using and adopting the technology. RFID technology is predicted to grow into a $2.1 billion industry by 2016 [2].

Following, the leading organization developing RFID standards, i.e. EPCglobal, is discussed and provides additional details on RFID standards, their usage and adoption. Most importantly, we are attempting to paint a picture how EPCglobal’s role-out of Electronic Product Code Information Services (EPCIS) provides a suitable infrastructure for the tracking and tracing of products, here pharmaceutical products or drugs in particular.

EPCglobal had been working for many years on the bar code [3], as well as its successor, RFID. In these efforts Electronic Product Code Information Services (EPCIS) was developed and has since become a widely used standard. EPCglobal is spearheading the development of industry-driven standards for the Electronic Product Code™ (EPC) in support of RFID in today’s fast-moving and information-rich trading networks. EPCglobal’s goal is increased visibility and efficiency throughout supply chains and higher quality information flow between companies and their trading partners [4].

EPCglobal describes this effort as follows: “The goal of EPCIS is to enable disparate applications to leverage Electronic Product Code (EPC) data via EPC-related data sharing, both within and across enterprises. Ultimately, this sharing is aimed at enabling participants in the EPCglobal Network to gain a shared view of the disposition of EPC-bearing objects within a relevant business context. … The EPC Information Service approach will define a standard interface to enable EPC-related data to be captured and queried using a defined set of service operations and associated EPC-related data standards, all combined with appropriate security mechanisms that satisfy the needs of user companies. In many or most cases, this will involve the use of one or more persistent databases of EPC-related data though elements of the Services approach could be used for direct application-to-application sharing without persistent databases. With or without persistent databases, the EPCIS specification specifies only a standard data sharing interface between applications that capture EPC-related data and those that need access to it. It does not specify how the service operations or databases themselves should be implemented. This includes not defining how the EPCISs should acquire and/or compute the data they need, except to the extent the data is captured using the standard EPCIS capture operations. The interfaces are needed for interoperability, while the implementations allow for competition among those providing the technology and EPC Information Service‖ [5]).”

We can see how EPCglobal’s EPCIS provides a suitable infrastructure potentially enabling tracking and tracing of products.

One vendor, IBM, has developed an elaborate framework within which RFID-based tracking and tracing, but also identity management and authentication is envisioned (see Fig. 1). IBM’s RFID Information Center (RFIDIC) [6] is based on EPCglobal’s EPCIS standard specification. Accordingly, this RFIDIC makes possible the tracking of uniquely identifiable, i.e. serialized,
products throughout the supply chain. Despite the name, the RFID Information Center is said to be sensor-agnostic, implying it recognizes product serialized with RFID, barcode and/or 2D barcode.

IBM’s RFIDIC Shipment Verification feature [6] offers an automated means to track shipments and confirm receipts. Automating these processes helps reduce product losses and the labor needed to resolve discrepancies and errors in shipment or receipt processes.

The following steps (see Fig. 2) demonstrate the Shipment Verification model [7]:

1. The retail distribution center ships totes to the retail pharmacy. Object events with a business step of shipping are sent to the RFID Information Center for the retail distribution center.

2. The retail distribution center responds to the subscription query from the retail pharmacy by sending a list of the totes that were shipped. These Advanced Shipping Notices (ASNs) provide advanced visibility of shipments in the form of Dashboards. The receiver's Expected Receipts dashboard highlights all in-transit totes so that labor can be scheduled for expected receipts. The shipper's Shipment Verification dashboard highlights all shipped totes that are eventually received to provide visibility of the downstream inventory. Electronic Product Codes (EPCs) in the delayed status (those not received in the expected time frame) can be investigated and the problems resolved.

3. The retail pharmacy receives the totes. Object events with a business step of receiving are sent to the RFIDIC for the retail pharmacy.

4. The retail pharmacy responds to the subscription query from the retail distribution center by sending a list of the totes received.

Fig. 2: RFIDIC Shipment Verification Feature

This EPCIC infrastructure must be viewed here in light of the motivation, the underlying interests and incentives of counterfeiters. We demonstrated earlier that counterfeiting is indeed financially rather enticing and attractive, especially vis-à-vis the penalties which are on balance relatively low. Organizationally and also physically we claim that there is relative easy access and entry to legitimate supply chains (from manufacturers through pharmacies and drug stores) within the PI, especially when considering the low level of supply chain controls on both the commercial and the customs sides. This occurs in spite of considerable uptake in control efforts by participants in the supply chain including such organizations as the Food and Drug Administration (FDA). This latter point will be addressed and demonstrated separately in a subsequent section.

Considerable gains have been made in supply chains in regards to visibility, transparency and control. These desirable features are now built into supply chain management software and have become standard features welcomed by numerous players within supply chains. Often such features make such manufacturing processes as just-in-time delivery possible in the first place. In many cases the practice of warehousing has become a concept from the past and in a way the trucks on the road and the containers on trains in transit to the manufacturer have become the substitutes of warehouses. Catching counterfeiters in such supply chain settings, however, is a difficult task. It requires deliberate cooperation and collaboration among almost all stakeholders in the supply chain, including such organizations as Customs and the FDA, in the design of architectures and processes as well as standard daily operations, the processing of transactions (physical (the handling of products) and digital (the processing of documents, payments, etc.).

Thus we realize that all of the above steps and measures are needed and require intensive cooperation and
collaboration to guard supply chains. In turn, such raised complexity and risks would raise the cost of counterfeiting considerably. Further below we will take a look at process changes that would increase the risk for counterfeiters. The next section presents two theoretical lenses via which this research is understood and explained conceptually.

Theoretical Perspectives of the Research

In the current research efforts we view this undertaking through a two-pronged theoretical lens: Transaction Cost Theory and Collective Action Theory. Both theories lend themselves nicely to understand and explain the present setting. The vast number of transactions carried out in the PI, especially those pertaining to sales and distribution, clearly may be viewed as applicable actions of Transaction Cost Theory. In order to introduce and apply measures of oversight and control, various regulatory efforts, the cooperation among a vast number of stakeholders (drug manufacturers, distribution companies, shipping companies, logistics firms, conventional drug stores, but also entities such as the FDA and Customs) is needed to make such collaborative efforts and tracking possible. This can only be accomplished when these stakeholders work cooperatively and collectively; thus Collective Action is the appropriate framework to consider here. Both theoretical approaches are briefly presented below.

Transaction Cost Theory

Transaction costs are costs incurred in making an economic exchange [7], [8], [9]. A number of different kinds of transaction can be identified:

Search and information costs are costs such as those arising in determining that the required good is available on the market, which firm has the lowest price, etc. Bargaining costs are the costs required to come to an acceptable and negotiated agreement with the other party in the transaction, drawing up an appropriate contract, etc. Policing and enforcement costs are the costs of making sure the other party in the transaction sticks to the terms of the contract, and taking appropriate actions (often through the legal system).

Transaction costs consist of costs incurred in searching for the best supplier/partner/customer, the cost of establishing a maximally developed contract, and the costs of monitoring and enforcing the implementation of the contract, i.e. transaction.

Transaction cost theorists assert that the total cost incurred by a firm can be grouped largely into two types—transaction costs and production costs. Transaction costs, often known as coordination costs [8], are well defined as the costs of "all the information processing necessary to coordinate the work of people and machines that perform the primary processes," whereas production costs include the costs incurred from "the physical or other primary processes necessary to create and distribute the goods or services being produced" [10].

The pharmaceutical industry and its supply chain setting cannot be seen alone within the context of pure transaction as envisioned through Transaction Cost Theory and as elaborated above. This setting is also characterized by cooperation, collaboration, negotiation, etc., i.e. activities whose very essence is embedded in the social nature of those efforts and tasks that are not typically captured by a Transaction Cost Theory perspective. For this we need to embrace Collective Action Theory described below.

The Theory of Collective Action

Collective Action refers to the pursuit of a common goal by more than one person. Presumably the achievement of the goal will then benefit all of society (e.g., Sandler, [11]). The term dates back to some of the work by Vilfredo Pareto in the 1930ies and Mancur Olson [12] as Olson applied this concept to economics subsequently in his The Logic of Collective Action: Public Goods and the Theory of Groups. To an extent Ronald Coase [7] should be mentioned in this context as well in that he provided in his classic The Nature of the Firm the concept of transaction costs making possible the measurement of the size of firms as well as the problem of social cost [13]. Accordingly, transaction costs, especially those pertaining to the cost of organizing of such collective action, for a majority attempting to achieve the utility of the goal (typically a public good) are disproportionately higher than the transaction costs for a small minority. Such a minority would benefit disproportionately more from such collective action. Sometimes this is referred to as a social dilemma and is explained by the utility yield being distributed via many individuals in the first case, but in the latter only very few individuals would benefit. An additional problem of collective action is the benefit gained by those who do not participate in its achievement. This is generally referred to as the free rider problem. The concept of collective action has been used extensively by several scholars in the standards evolution, standards diffusion as well as standards adoption literature (e.g., Markus, Steinfield, Wigand & Minton, [14]; Wigand, Steinfield & Markus, [15]).

These two theoretical perspectives, Transaction Cost Theory and Collective Action Theory, permit a two-pronged view of the research covering suitably the transaction-focused nature as well as more social-focused activities in the PI and its corresponding supply chain environment.

Following we present a rather poignant example within the PI illustrating nicely the sequential transactions, but also
their severe and sad consequences, when counterfeiting goes awry on an international scale.

**A Poison’s Path**

Here we present one case of trafficking in fake goods, specifically a pharmaceutical intermediate product (glycerin) produced to be used eventually in the manufacture of various pharmaceutical products, here specifically, heparin. This brief case study illustrates well how this setting of distributing fake products very quickly is international in nature, how at the core of the issue is identity management and authentication as well as how consequences of such fraud may result in the disfigurement and even over 80 deaths in patients worldwide.

In 2007, a popular blood thinning drug, heparin, was found to contain a mysterious ingredient. This ingredient was only discovered after multiple cases of severe allergic reactions, and even deaths, occurred upon taking the drug. Forensic tests and examinations were conducted to determine the cause. The FDA determined that some heparin contained a substance mimicking the real drug, but was a counterfeit instead [16]. The FDA linked 19 deaths in the U.S., and hundreds of severe allergic reactions directly to this counterfeit drug [17]. Through intense investigation the journey of the contaminated heparin was traced back to its origin - to a small factory in Hengxiang, China [16], (see Figure 1). The chemicals used were prime ingredients for anti-freeze. They were sold, instead, as a type of glycerin used in the production of heparin. For each step in the transactions as the fake product was sold, separate and unique certificates assuring the product’s identity and authenticity were issued (see Fig. 2). Chinese authorities arrested the person believed to be responsible, Wang Guiping, and sentenced him to life in prison in September of 2009 [16]. This is, however, just one of many examples of how a counterfeit drug was discovered in the international as well as U.S. pharmaceutical supply chain.

<table>
<thead>
<tr>
<th>Ref</th>
<th>Action</th>
<th>Result</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>Glycerin created in Hengxiang, China</td>
<td>Sold a syrup containing diethylene glycol, a toxic industrial solvent and prime ingredient in some antifreeze, to Beijing broker using forged documents</td>
</tr>
</tbody>
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| 2 | Shipped from port in Shanghai to Barcelona, Spain | Purchased by a new broker, assuming original documentation was authentic, gave additional stamp of authenticity. Resold to broker in Panama |
| 3 | Shipped 46 barrels to Colon, Panama | Panamanian government assumed barrels certificates of authenticity were real and purchased for medicinal use |
| 4 | Shipped by truck to Panama City, Panama | Government officials used syrup in 260,000 bottles of medicine |
| 5 | Medicine dispersed throughout Panama’s medical community and pharmacies | At least 100 deaths in Panama are blamed on this counterfeit glycerin, causing numerous severe allergic reactions, with some patients suffering permanent damage, i.e. facial paralysis. In China, at least 81 deaths were blamed on the drug |

Figure 1: A Poison’s Path


The pharmaceutical industry is of course not the only business with counterfeiting problems. In 2009 U.S. officials captured a total of about $260 million in fake products [18]. This is not just a problem in the United States but this phenomenon is observable worldwide.

Chinese criminal gangs are the biggest purveyors of fake products in the United States, accounting for about 80% by value of the counterfeit goods seized last year, according to U.S. government data. Footwear tops the list of fake goods, followed by consumer electronics, luxury goods, and pharmaceutical products [18].

The single, biggest sweep against counterfeit goods had taken place in December 2009, when federal officials confiscated about $26 million worth of fake toys, Christmas ornaments, perfume, and electronics [18]. Since then, U.S. officials said they made their biggest-ever seizure of
counterfeit goods in April 2010 in two operations yielding more than $240 million in total as part of a broader federal offensive against the buying, selling and transacting of pirated products [18]. In this large-scale sting operation, federal, state and local law enforcement officials (including U.S. Immigration and Customs Enforcement (ICE), at the Department of Homeland Security), part of the National Intellectual Property Rights Coordination Center, confiscated about $40 million worth of counterfeit goods, including fake Rolex watches, Coach handbags, and Nike shoes, as well as pirated DVDs and fake pharmaceutical products, in a sweep of more than 30 U.S. cities.

This massive effort to reduce and yet better to eliminate the trafficking of fake goods, reminds the world business community that fake products, in turn, steal jobs, creativity, benefits derived from entrepreneurship and innovation. It funds organized crime and there is a serious risk to public safety.

![Fig. 2: False certificates of authentication were issued for each step the fake product was sold.](Image)


According to ICE, the "next big frontier" is Web sites offering pirated movies, music, and pharmaceutical products [18].

It is readily evident that counterfeiting of goods is a major worldwide problem and must be faced by the U.S. just the same. Counterfeiting is especially problematic when dealing with pharmaceutical products such as drugs and when patients’ safety, well-being and even their very lives may be at stake. Various stakeholders within the PI and its supply chains have become very concerned about such practices and have joined efforts to curtail the production and distribution of counterfeit drugs. Such efforts require cooperation and collaboration, and they suggest deliberate collective action among the relevant players in this setting, including governments and regulators, pharmaceutical manufacturers, wholesalers, importers, pharmacies and patients. A call for such collective action is presented below.

### Regulatory Efforts: A Call for Collective Action

First we present an effort made by European researchers who have examined stakeholders’ interests and concerns about counterfeit drugs in supply chains. This research is part of a multi-year effort (2006 to 2010) funded by the European Union. The project’s title is Information Technology for Administration and Intelligent Design of E-Government (ITAIDE). Among the project’s aims are recognizing that one of the great challenges for European governments is solving the paradox of increasing security of international trade, while at the same time reducing the administrative overhead for commercial as well as public administration organization. It is vital to have timely information about business transactions. Such information gathering is very costly for businesses and public administrations. Finding the right balance between control and cost of information gathering is the key to increase competitiveness of European businesses locally, nationally and internationally. ITAIDE looks at various industry settings (beer, paper and food), including the distribution of drugs in the PI in Europe. The increasing threat of counterfeit drugs is the focus on this part of the overall ITAIDE project. Here researchers are looking at how to increase security and control of supply chains with the aim of patient safety being one of the central questions in this context. Accordingly, not only potential technologies, e.g., tracking and tracing, are considered, but also the coordination and orchestration of organizational and legislative issues are part of the analysis.

These researchers delineated the interests, incentives and concerns of the various stakeholders in the drug supply chain setting, including governments, agencies, regulators, manufacturers wholesalers, importers, pharmacies and patients [19].

Numerous governmental agencies have stepped forward in attempts to ensure patients’ safety when purchasing legitimate drugs for their ailments. At the international level, the following organizations are active in these efforts.

They include:
- International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
- Uppsala Monitoring Care
- World Health Organization
- Council for International Organizations of Medical Sciences
- Single Convention on Narcotic Drugs

At the U.S. national level we can mention the following:
- U. S. Department of Health & Human Services
Several laws and acts were created providing enforcement authority to various government agencies:

- Food and Drug Administration
- Drug Enforcement Administration
- Center for Drug Evaluation and Research

Following we would like to present briefly a few selective highlights that characterize these anti-counterfeiting efforts of drugs.

Impressive strides have been made by the FDA and its Office of Criminal Investigations (OCI). Some of these efforts were enhanced by the Prescription Drug Marketing Act (PDMA) of 1987 [20]. The PDMA is a law of the United States federal government establishing legal safeguards for prescription drug distribution to ensure safe and effective pharmaceuticals. This law is designed to discourage the sale of counterfeit, adulterated, misbranded, subpotent, and expired prescription drugs. It was created in response to the development of a wholesale sub-market (the so-called “diversion market”) for prescription drugs. The PDMA was modified by the Prescription Drug Amendments of 1992 [20] on August 26, 1992. The FDA has issued regulations implementing the PDMA in 1990 [20] and 1999 [20]. Moreover, the FDA has embraced the adoption of electronic tracking and tracing technologies such as RFID.

On numerous occasions the FDA has praised RFID as a technology as the most promising approach to provide reliable and timely track and trace information. The FDA endorsed RFID technology in 2004 and had hoped that by 2007 the adoption and common use of reliable track and trace technology would be feasible and thus would help secure the integrity of the drug supply chain by providing an accurate drug “pedigree” or a drug’s life history. An RFID-based feature, the ePedigree is an optional add-on component that enables manufacturers, wholesalers, and retailers to generate an electronic pedigree, or life history, of a pharmaceutical product moving through the supply chain. PDMA established minimum standards for State licensing of wholesale distributors of prescription drugs and requires unauthorized wholesale distributors to provide purchasers with a declaration (i.e. a pedigree) identifying each prior sale of the drug. Many stakeholders argued that this requirement would result in economic hardship for wholesalers who will have to provide such pedigrees.

It should be noted that electronic track and trace capabilities, including RFID, by themselves are not the solution to combating counterfeit pharmaceutical products. It seems that more sophisticated applications such as a multilayer approach, using yet other technologies securing the product as well as packaging, including holograms, color-shifting inks, etc. will be needed. Technology alone though is not the answer either. It is apparent that increased awareness and vigilance, stiffer penalties and increased State efforts will be needed to stay on top of current counterfeit threats. Clearly though, widespread adoption of electronic track and trace technology would help the stakeholders in the supply chain as well as patients and doctors surpass the goals set in the PDMA.

Conclusions and Outlook

In this research, the authors examine information management and tracking of drugs in supply chains within the pharmaceutical industry. Identity management and authentication are viewed as fundamental components of information management. The field of study addressed in this setting is regarding counterfeit drugs, a dilemma of paramount importance for public health and the well-being and safety of patients. The authors advocate RFID and related technologies, including EPCglobal’s Electronic Product Code Information Services (EPCIS) and IBM’s RFID Information Center system that, in turn, provide a suitable infrastructure for the tracking and tracing of uniquely identifiable, i.e. mass-serialized, products throughout the supply chain. The theoretical framework of Transaction Cost Theory and Collective Action Theory is presented using a two-pronged approach to conceptually show the present research setting. Several regulatory efforts and compliance regimes are presented and a call for collective action for all stakeholders within the supply chain in the pharmaceutical industry is advanced.

The authors recognize that the pharmaceutical industry is a large complex web of corporations, legislation, regulatory efforts, compliance regimes, manufacturers, wholesalers, pharmacies, importers as well as rapidly advancing technologies and applications. Counterfeit drugs are a major problem for public health, the concern of doctors trying to help as well as the well-being and safety of patients. Drug counterfeiting no longer is a concern in a given country or region; it is truly an international problem as drug suppliers around the globe feed their raw and intermediate products into the global drug supply chain. Considerable gains have been made in supply chains in regards to visibility, transparency and control. More and more such desirable features are built into the supply chain management software, have become standard features welcomed by numerous players within the supply chain.
who, in turn, benefit from these features and they have made the life of counterfeitters more difficult.

This situation, however, is yet more difficult when considering the comments of one reader (Dr. Marv Shepherd) to a Wall Street Journal article entitled, “China never investigated tainted Heparin, says Probe” [21]:

I'm not surprised. When I was in China in 2008 and again in 2009 talking to Chinese about the counterfeit drug problem. One Chinese FDA official told me and I quote: "... our drug exports are not our problem they are your (U.S.) problem." This summed it up very well for me.

Catching counterfeiters in such supply chain settings, however, is a difficult task. It requires cooperation and collaboration among almost all stakeholders in the supply chain, together with such organizations as Customs and the FDA in the design of architectures and processes as well as standard daily operations, including the processing of transactions (physical (the handling of products) and digital (the processing of documents, payments, etc.). Thus we realize that all of the above steps and measures are needed and require intensive cooperation and collaboration to guard supply chains. In turn, such raised complexity and risks would raise the cost of counterfeiting considerably. Moreover, it is apparent that increased awareness and vigilance, stiffer penalties and increased government efforts will be needed to stay on top of current counterfeit threats. Although we presented a number of very promising technical solutions such as RFID, Electronic Product Code Information Services (EPCIS) together with the RFID Information Center system as well as the various ePedigree efforts that together indeed can function as a suitable infrastructure providing tracking and tracing capabilities, the solution, however, is not solely a technical one. The counterfeit drug problem is also an organizational and a people problem. This, in turn, requires cooperation and collaboration, i.e. indeed collective action, among all the many stakeholders within the supply chain. It is clear that this is an industry-wide as well as an interorganizational concern requiring coordinated efforts, i.e. collective action, including industry, government, third-party representatives as well as supranational organizations.

References