

EFFICIENTLY OVERSEEING AND MONITORING DATA WITHIN THE PHARMACEUTICAL SUPPLY CHAIN

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ABSTRACT: The authors conduct research into pharmaceutical inventory management and data handling practices. Fake pharmaceuticals pose a serious threat to the well-being of patients when this occurs. The authors advocate for the use of radio frequency identification (RFID) and related technologies, such as EPC Global's EPCIS and IBM's RFID Information Center, to monitor the movement of mass-produced, uniquely marked commodities across the supply chain. This situation is analyzed with the help of Transaction Cost Theory and the Theory of Collective Action. Everyone involved in the distribution of pharmaceuticals must act lawfully and cooperate without interruption.

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

1. INTRODUCTION

It's in everyone's best interest for businesses to practice good material management. Drugs are included in the article. In order to verify the authenticity of drugs and components, Principal Investigators (PIs) must be adept with managing and monitoring data. Your employment requires something of you. When purchasing medications from a store, customers frequently neglect to take necessary precautions. The introduction of counterfeit medications and chemicals into the US pharmaceutical supply chain is a serious issue. The issue of counterfeit pharmaceuticals in the PI will be discussed, along with the potential role that RFID and other technology could play in addressing this issue. What's more, you can set your own benchmarks if you so choose.

RFID technology and modifications to the PI could be utilized to prevent the distribution of counterfeit medications. Data for this study came from the Food and Drug Administration, the World Health Organization, the Wall Street Journal, and the New York Times. According to these reports, preventing fraudulent pharmaceuticals from reaching patients simply

requires putting in place identity control and verification measures. RFID and the supporting infrastructure can be used to trace counterfeit medications from their point of origin to the point of sale, as demonstrated by their work. Several methods, including verifying the authenticity of pharmaceutical products with IM (Identity Management) and RFID (Radio Frequency Identification) technology, are discussed in this article to combat the sale of counterfeit medications.

The first section of the research provides a high-level review of identity management and authenticity as foundational tenets of data management. This brief article explains how RFID and other similar technologies, such as the Electronic Product Code Information Services (EPCIS) infrastructure, can be utilized for these purposes. Then, we use the Transaction Cost Theory and the Collective Action Theory to take a fast theoretical and conceptual look at our findings. The next step is to analyze the paper's central argument. After making a last comment, our task is complete.

Information Management: Identity Management and Authentication

Managing identifiers entails amassing and cataloguing data pertaining to individuals, locations, and objects. This has scientific and preventative applications. Most banks need identification when depositing a check. What differentiates one thing from another doesn't matter much. Nail techs might not give much thought to the origin of the metal they employ. In order to determine what's causing the disease, the cattle industry needs to know where each animal comes from. These occurrences illustrate how organizations' approaches to identity management can vary.

As a means of determining credibility. In addition, it can verify the authenticity and origin of a product. If you want to know if something is authentic, look at how it compares to the creator. Picasso is highly regarded in the art world. The impact of passing fads and the length of time required to complete an artwork will be discussed, followed by methods of controlling and verifying one's identity.

2. RFID, EPCIS AND A RFID-BASED INFRASTRUCTURE

There is an immediate need to investigate RFID technology's potential for reducing fraud and improving the efficiency of stock management. RFID has been around for quite some time. Radar was developed and employed during WWII to detect and distinguish between aerial enemies and allies. Recently, Walmart has been employing RFID technology to monitor its supply chain. Using RFID readers simplifies the process of product labeling for factories. There are numerous varieties of processors, including palette processors, case processors, and item processors. The authenticity of a product can be verified with this label.

Tags can be both read and ignored

simultaneously. Passive keywords tend to have a lower success rate. Passive tags are used when agents make requests. It generates a powerful electric field to transmit identification information. A reader-capable RFID chip. Passive tags are more commonly employed than active identifiers because of their lower cost. Stickers like these can be used to hold important information such as license numbers, product IDs, and more. Serial numbers are used to verify the authenticity of a product and provide useful details like the manufacturing date. The lives of many people may be saved if we knew how narcotics were distributed. RFID products are undergoing standardization and refinement, and businesses are keen to adopt them. By 2016, it is anticipated that RFID sales would have generated over \$2 billion.

EPC global is the go-to resource for information about RFID standards, uses, and applications. EPC global is the primary organization responsible for defining RFID technology. We need to demonstrate how EPCIS is put to use by EPC in the global tracking and control of items, particularly pharmaceuticals.

EPC global has stopped producing RFID tags and bar codes for some time now. EPCIS's profile has risen thanks to these initiatives. EPC globe's primary objective is to promote industry-set RFID EPC standards in information-intensive business networks. The purpose of EPC is to improve transparency, productivity, and information exchange along the supply chain.

EPC global describes this effort as follows:

EPCIS streamlines the transfer of EPC information across businesses. According to the EPC global Network, this information is useful for users to gain a better grasp of how EPC-bearing devices function in the workplace. Establishing a consistent path to and from EPC

data is the primary objective of the EPC Information Service. To accomplish this, we will clarify service operations, standardize data standards, and implement security measures that are suitable for both customers and companies. In most cases, this is achieved by linking a single, permanent database to EPC. The Services architecture allows for the transfer of information across applications without the need for persistent databases. EPCIS allows apps to exchange EPC-related data without consideration to the data's persistence. There is no database setup or service procedures provided. As a result, EPCISs shouldn't be taught to gather and analyze data in ways that are forbidden by EPCIS regulations. Technology and EPC Information Service providers benefit from application and interoperability because it facilitates competition.

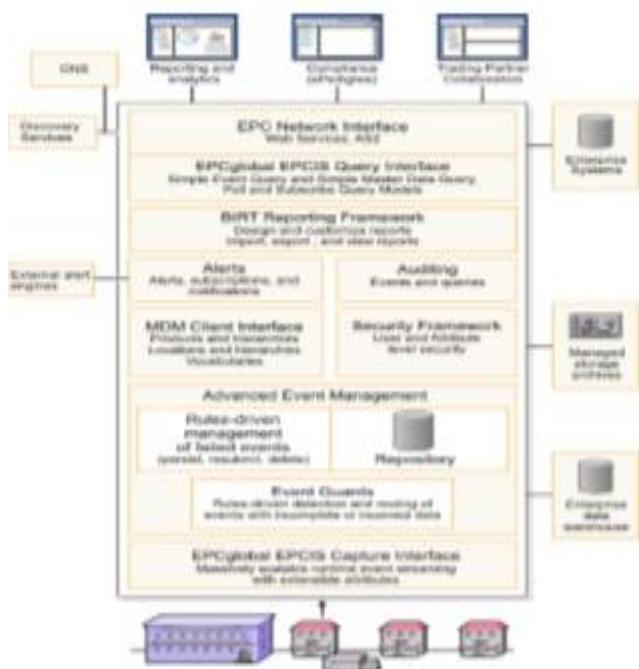


Fig. 1: RFID Information Center System

IBM use radio frequency identification (RFID) tags for these purposes. IBM's RFID Information Center (RFIDIC) makes extensive use of EPC EPCIS [6]. This Radio Frequency Identification Integrated Circuit (RFIDIC)

monitors and records the distribution of specific items. No matter what kind of sensor is being utilized, the RFID Information Center can locate the corresponding item.

With the help of the IBM RFIDIC Shipment Verification for RFID InfoCenter System, you can keep tabs on your deliveries and know for sure when they were delivered. By eliminating human intervention in the shipping and receiving processes, product loss is reduced and labor costs are reduced.

As can be seen in Figure 2, the Shipment Verification procedure consists of the following steps:

Distribution centers allow for speedier delivery of containers to retail pharmacies. The RFID Information Facility tracks shipment-related events at the distribution facility.

To streamline the shipping process, retail delivery services have pharmacies join waiting lists for shipping containers. ASNs allow researchers to examine cargo containers. Users can observe the sequence of nodes that follows a received or broadcast container in the Verification interface. EPCs can be reviewed and revised after the fact.

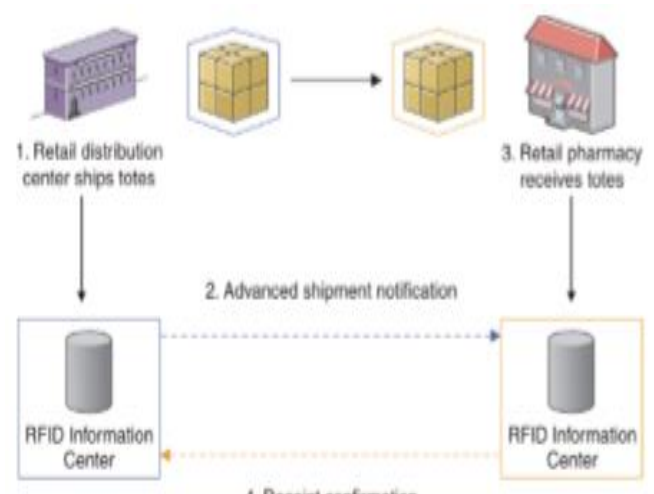


Fig. 2: RFIDIC Shipment Verification Feature
Source: IBM RFID Information Center. See

The IBM RFID Information Center is where the data came from. Look for

Backpacks are sold in pharmacies. When items with business implications are purchased and handled, information is transmitted to the pharmacy's RFIDIC (Radio Frequency Identification Integrated Circuit).

As part of a subscription service, the retail pharmacy will ship containers to the retail distribution center upon request.

The IBM RFID Information Center is the place to go for shipping certifications. Look for

When analyzing this EPCIC system, it is crucial to consider the motivations, benefits, and outcomes that counterfeiters seek. As we've shown, counterfeiting may be rather lucrative if the consequences are minimal. Manufacturers, pharmacies, and other suppliers in the PI legal supply networks can be found and joined with relative ease. Especially when supply chains violate trade and practice regulations. This issue persists despite the implementation of supply chain restrictions imposed by organizations like the Food and Drug Administration (FDA). This issue will be addressed in a forthcoming section.

Increased transparency and openness throughout the supply chain. The addition of these crucial services to supply chain management software has been welcomed by many in the field. Just-in-time delivery is a typical tactic used by companies. Some companies use railroads for transporting cars and containers rather than relying solely on warehouses for this purpose. Because supply networks are so complex, it is difficult to track down counterfeiters. When it comes to monitoring digital and physical actions, such as the movement of items, the FDA and Customs must collaborate to establish systems and procedures.

It is crucial that the following regulations and legislation be implemented simultaneously to ensure the safety of traffic corridors. It would be too expensive to copy due to the hazards and

difficulty involved. The following sections examine the evolution of methods that facilitate forgery. In the following section, we will compare and contrast two theoretical perspectives on this matter.

3. THEORETICAL PERSPECTIVES OF THE RESEARCH

This research makes use of the theoretical frameworks of Collective Action Theory and Transaction Cost Theory. These two concepts are pertinent to the current situation. When it comes to business operations like sales and marketing, the Transaction Cost Theory is a huge help to PI. Standardization and enforcement of those rules requires cooperation between shipping firms, transportation companies, pharmacies, and government agencies including the Food and Drug Administration and Customs and Border Protection. Collective action is effective because it requires many groups to work together to achieve their aims. This brief article provides a summary of the two theoretical perspectives.

Transaction Cost Theory

Economic trade expenses are the costs incurred by a business while engaging in economic exchange. These charges include the time and effort spent researching factors unique to each transaction, such as availability and pricing. It costs money to communicate, to make contracts, and to provide ancillary services. Keeping an eye on the contract and initiating legal action if the other party breaches it are both costs associated with law enforcement and control.

Transaction costs include the time and effort required to source a suitable service, partner, or consumer, and to negotiate and execute a satisfactory contract.

The costs of running a business can be split into

two categories, transaction costs and product costs, according to their statement. Transaction costs are the costs associated with coordinating economic activities. All the processing of data required to coordinate the activities of humans and machines in order to close a deal is included.

Physical labor is included in the production costs since it is essential to the creation and sale of the product.

In light of Colle's proposal, we must examine the pharmaceutical market and supply chain through his eyes. From this vantage point, the value of socially dependent tasks like teamwork and negotiating increases.

The Theory of Collective Action

Joint action refers to the collaborative efforts of multiple individuals toward a single objective. Getting the job done could be beneficial for everyone (Sandler). For the first time, in their 1930s economics book "The Logic of Collective Action: Public Goods and the Theory of Groups," Wilfred Pareto and Mancur Olson coined the word. To understand the role of large corporations in modern society, Ronald Coase turned to the concept of transaction costs, which he introduced in his book "The Nature of the Corporation." The majority faces more transaction costs than the minority when attempting to aid the public, particularly when it comes to arranging group actions. Cooperation amongst this tiny group is crucial. The outcomes of various scenarios will be beneficial to various individuals. The outcomes of these two scenarios will be beneficial to different people. Dual-sided social gathering. Members of the group action who are incompetent at their tasks exacerbate the situation. This phenomenon is commonly referred to as the "free rider problem." Researchers Markus, Steinfeld, Wigand, and Minton examined the processes by which standards are adopted, spread, and authorized.

Together, Transaction Cost Theory and Collective Action Theory provide a comprehensive lens through which to examine individual and group behavior in PI and supply chain settings.

The PI's shady example of the problem demonstrates how widespread counterfeiting could complicate business in the future.

4. A POISON'S PATH

A dishonest drug broker has exposed the illicit heparin-to-glycerin trade. This case study illustrates the need of managing and verifying your name, the prevalence of counterfeit items, and the impact of fraud on the lives of more than eighty patients around the world.

An unidentified compound was found in heparin in 2007. Several fatal allergic reactions led researchers to the drug's key component. The motive for the crime was discovered during the investigation. The FDA discovered a drug ingredient in the counterfeit heparin. The Food and Drug Administration has linked the use of this counterfeit drug to 19 fatalities and other adverse consequences in the United States. Heparin was determined to be contaminated following a thorough study of a seemingly typical building in Hengxiang, China (Figure 1). It's crucial to have antifreeze. Glycerin might serve as a precursor to heparin. Figure 2 revealed that the counterfeit product was in fact genuine and authentic for each purchase. Since his capture in September 2009, Wang Guiping has been serving a life sentence. In the United States and other countries, fake medications have been discovered in drug distribution systems..

1		showing syrup was 99.5% pure glycerin
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
	After thorough worldwide investigation, contaminated drugs linked to Chinese citizen: Wang Guiping	Receives life sentence in Chinese prison for his crimes

Figure 1: A Poison's Path

The problem of counterfeit pharmaceuticals is not unique to the pharmaceutical industry. In 2009, US authorities confiscated counterfeit goods with a market value of \$260 million. Indeed, this is a major issue. U.S. data shows that in 2013, criminal organizations in China were responsible for the sale of 80 percent of all counterfeit items. Following closely behind sneakerheads are the tech, luxury, and drug communities. In December 2009, the federal government made its largest seizure of counterfeit goods, including toys, decorations, fragrances, and gadgets, estimated at \$26 million. About \$40 million worth of

counterfeit goods were seized in April 2010 by federal, state, and local law enforcement agencies, including ICE at DHS. This included counterfeit Rolex watches, Coach handbags, Nike shoes, pirated DVDs, and bogus medicinal supplies. This operation targeted around 30 different US locations as part of a larger study of piracy.

Companies should be aware that selling counterfeit goods has a negative economic impact, discourages innovation, and makes it more difficult to launch a new venture. It's not just risky, but facilitates the growth of organized crime as well.



Fig. 2: False certificates of authentication were issued for each step the fake product was sold.

When it comes to illegal activity, ICE sees counterfeit pharmaceuticals, music, and media as the "next great frontier."

It is very clear that the United States must take action against the global spread of counterfeit goods. Theft of pharmaceuticals is especially heinous when it puts the lives and well-being of patients at danger. Together with its supply chain partners, PI is aiming to eliminate the production and distribution of counterfeit pharmaceuticals. All stakeholders, including governments, regulators, pharmaceutical firms, distributors, importers, pharmacies, and

patients, will need to collaborate for success. The next step is to issue a call to action.

5. REGULATORY EFFORTS: A CALL FOR COLLECTIVE ACTION

Experts in Europe first investigate supply chain members' concerns regarding counterfeit pharmaceuticals. From 2006 till 2010, the European Union funded this investigation. According to ITAIDE's research, Europe should strike a middle ground between the regulation of enterprises and the government and the security of international trade. Interesting corporate deals have been made recently. The cost of data collection is high for both businesses and governments. Europe's businesses must strike a balance between the expenses of data collection and data security if they are to remain competitive on a regional, national, and international scale. Europe's drug, alcohol, paper, and food supply chains are all monitored by ITAIDE. The ITAIDE initiative works to combat the distribution of counterfeit pharmaceuticals. The safety of patients is a top priority, so researchers are investigating supply chain management and protections. Instruments for legislative and governmental cooperation, orchestration, and oversight are investigated.

The medication supply chain includes manufacturers, wholesalers, importers, retailers, hospitals, doctors' offices, patients, and regulatory agencies. There are a number of government organizations that watch out for persons who use pharmaceuticals. There are international networks. CMS, FDA, DEA, CDER, and FDA are just some of the government agencies that have assisted law enforcement and criminal investigations. These endeavors benefited from PDMA 1987 funding. The PDMA regulates the distribution of medicines throughout the United States to guarantee their quality and safety. According to

this statute, it is illegal to sell prescription medications that are out of date, ineffective, altered, mislabeled, or counterfeit. Demand for illegally obtained pharmaceuticals. The 1992 Amendments modified the PDMA. In 1990 and again in 1999, the FDA released recommendations about PDMA. RFID is used by the FDA.

RFID, according to the FDA, is the most efficient and reliable method of data tracking. RFID technology received FDA clearance in 2004. The FDA anticipates widespread adoption of track and trace technology by 2007; this would allow for the visualization of a drug's pedigree by that year. Because of this innovation, drug distribution channels will remain secure. RFID allows pharmaceutical manufacturers, wholesalers, and retailers to track the distribution of their products. Those in the pharmaceutical wholesale and distribution industry who were not already registered were required to do so and provide details of their business dealings. Many people are concerned about the future of pedigree merchants.

No amount of RFID tags or other sensors will prevent the sale of counterfeit medications. Holograms, intricate coatings, and color-changing dyes all contribute to the security of packaging. In and of itself, technology is insufficient. Education, inspections, fines, and government support are all necessary to combat the sale of counterfeit goods.

6. CONCLUSIONS AND OUTLOOK

This article discusses the need of keeping tabs on pharmaceuticals and the pharmaceutical supply chain. Identifying and authenticating users is a must for every information management system. Patients and the general public are at risk from counterfeit drugs, according to research. It is suggested that radio frequency identification (RFID) and related technologies, such as IBM's RFID Information

Center and EPC Global's EPCIS, be used to monitor the distribution chain of serialized, individually recognizable products. Transaction cost theory and collective action are the current hot topics in economics. The law mandates open communication between all links in the pharmacy supply chain.

The pharmaceutical industry is a complex web of interconnected businesses, regulations, laws, compliance procedures, suppliers, retailers, buyers, sellers, and new and emerging technologies and applications. Falsified drugs pose a threat to both doctors and patients. Basic and intermediate materials for fake drugs are sourced from worldwide pharmaceutical distributors. The modern supply chain is transparent and simple to manage. Stakeholders in the supply chain place a premium on unique supply chain management software.

Dr. Marv Shepherd of the Wall Street Journal claims that China did not investigate the tainted heparin and that the remarks made by the investigation just serve to further complicate matters.

Not a bit shocked. In 2008 and 2009, I worked to stop the sale of counterfeit Chinese medicine. An official with the Chinese FDA said it best when he or she said, "Our drug exports are not our concern; they are your (US) problem."

Fraud in the supply chain is difficult to detect. The majority of supply chain participants, including Customs and the FDA, must collaborate on the development of architectures and processes, as well as the execution of routine digital and physical transactions (such as the handling of items). Supply chain security relies on the participation and cooperation of humans in all processes and regulations. Forging is quite expensive since it is risky and difficult to accomplish. Fake threats can be stopped if more people are aware of them, maintain tabs on them, punish those responsible, and involve the authorities.

EPedigree, RFID, EPCIS, and the RFID Information Center aren't the only novel approaches to tracking and monitoring. Drug counterfeiting has repercussions for both consumers and manufacturers. The supply chain as a whole needs to coordinate their efforts. It will take cooperation between businesses, states, expats, and international organizations to find a solution to this issue.

REFERENCES

1. Millett, L. I. and Holden, S. H., Authentication and its privacy effects, *Internet Computing, IEEE* , Vol. 7, No. 6, pp. 54- 58, Nov.-Dec. 2003.
2. History of RFID., *RFID Journal*, [Online] 2010, <http://www.rfidjournal.com/article/articleview/1338/1/129/> (Accessed: 29 January 2011).
3. Brown, S. A. (1997). *Revolution at the Checkout Counter: The Explosion of the Bar Code*. Cambridge: Harvard University Press.
4. EPCglobal., EPCglobal, [Online] 2010, <http://www.epcglobalinc.org/about/> and <http://www.gs1.org/epcglobal>, (Accessed: 29 January 2011).
5. EPC Information Services (EPCIS) Version 1.0.1 Specification., EPCglobal, [Online] 2010.
6. <http://www.epcglobalinc.org/standards/epcis> (Accessed: 29 January 2011).
7. IBM RFID Information Center. [Online] http://en.wikipedia.org/wiki/IBM_RFID_Information_Center, (Accessed: 29 January 2011).
8. Coase, R. . *The Nature of the Firm*. *Economica* 4, 1937 (November), pp. 386–405. Williamson, O. *Transaction-Cost Economics: The Governance of Contractual Relations*, *Journal of Law and Economics*, 1979, Vol. 22, No. 2, pp. 233-261.
9. Wigand, R. T., Picot, A., and Reichwald, R. (1997). *Information, Organization and Management: Expanding Markets and*

Corporate Boundaries. Chichester, England:
Wiley.

10. Wigand, R. T. and Benjamin, R. I.
Electronic Commerce: Effects on Electronic
Markets. Journal of Computer- Mediated
Communication, 1996, Vol. 1, No. 3.
[Online],
<http://jcmc.indiana.edu/vol1/issue3/wigand.html>
(Accessed: 29 January 2011).