Improving the Transparency of the Pharmaceutical Supply Chain Through the Adoption of Quick Response (QR) Code, Internet of Things (IoT), and Blockchain Technology: One Result: Ending the Opioid Crisis

Justin D. Evans

Abstract

Over the past two years, Americans in nearly every state have suffered adverse effects from counterfeit medications, many of whom have died. The main culprit is Fentanyl-tainted counterfeit opiates which often lead to fatal overdoses. The increasing epidemic of counterfeit prescription medications extends beyond social classes, gender, race, and age. For instance, pop star Prince recently overdosed on counterfeit Hydrocodone containing synthetic Fentanyl. Shockingly, one in ten medications sold in developing countries are counterfeit; either containing incorrect doses of active ingredients or containing toxic contaminants retained from the production process. The popularity of counterfeit medications stems from cheaper costs, but also because of the ease with which these counterfeit products can be purchased. While the blockchain has gained its fame from Bitcoin, its potential implications are far reaching. In this paper, I propose the use of QR code and the IoT (Internet of Things) sensor devices leveraging the blockchain for increased transparency of the pharmaceutical supply chain and manufacturing process. The data collected from the devices would then be transferred to the blockchain, enabling consumers to use an app to verify the provenance of their medication.

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Justin D. Evans[*]

I. INTRODUCTION: THE PROBLEM

Counterfeit medications have become one of the most complex and challenging problems that modern societies face across the globe. Many entities are tasked with protecting pharmaceutical consumers, including both national governments and pharmaceutical companies. In this Article, counterfeit drugs are defined as being substandard, spurious, falsely labeled, or falsified medicines, making it difficult to identify whether the medication is a genuine product.[1] Though there have been developments in technology already applied to the industry, which one would believe should mitigate the spread of counterfeits, the dangers that counterfeit medications present to global public health has increased. Between 2005 and 2010 the theft of pharmaceuticals increased by 66%, and the incidence of counterfeit medication use/production increased by 122% during this same period of time.[2]

The prevalence of counterfeit drugs arises from the failure to secure the integrity and safety of pharmaceutical companies' global supply chains.[3] These global supply chains are often disrupted by large transnational crime organizations.[4] There are two general forms of supply chains: 1) a legitimate supply chain defined

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[1] *Counterfeit Medicine*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/counterfeitmedicine (last updated Aug. 12, 2016).

[2] Tim K. Mackey et al., *Counterfeit Drug Penetration into Global Legitimate Medicine Supply Chains: A Global Assessment*, 92 AM. J. TROPICAL MED. HYGIENE 59, 59 (2015).

[3] *Id.*

[4] *Id.*

as any supply chain that is regulated by a regulatory body with the expectation that the product is authentic and is coming from the manufacturer; and 2) an illicit supply chain which is any supply chain that originates from any establishment without regulatory supervision, such as bodegas or the internet.[5]

Between 2009 and 2011, there were 1,799 different incidents in which counterfeit drugs were found to penetrate legitimate supply chains.[6] These incidents were reported by internal pharmaceutical employees, open source reports, liaisons, and joint investigative agencies.[7] A recent study revealed that 58% of all counterfeit medications were anti-microbial anti-infectives, cardiovascular, central nervous system, or alimentary medications. These were the most reported counterfeited classes of medications due to their demand.[8] Interestingly, incidents in China, Peru, Uzbekistan, Russia, and Ukraine make up 65.7% of all those reported.[9] This study revealed that 127 of 196 countries globally had not reported any incidents of counterfeit medication use, presumably due to the lack of effective regulation.[10]

Counterfeit drugs are frequently manufactured under unsafe conditions, which increases the chances of contaminants being incorporated in the drug and often do not contain the appropriate amount of the active ingredient.[11] Counterfeiters have been found to include toxins like rat poison, road tar, concrete, chalk, boric acid, and solvents such as DMSO in their products which can result in adverse reactions or death.[12] In fact, counterfeit medications for malaria and tuberculosis are said to account for over 700,000 deaths annually in developing countries.[13]

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[5] THE KAISER FAMILY FOUND., *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain* (Mar. 2005), https://kaiserfamilyfoundation.files.wordpress.com/2013/01/follow-the-pill-understanding-the-u-s-commercial-pharmaceutical-supply-chain-report.pdf.

[6] Mackey et al., *supra* note 2, at 61.

[7] Mackey et al., *supra* note 2.

[8] *Id.* at 62.

[9] INT'L MED. PRODS. ANTI-COUNTERFEITING TASKFORCE, *Counterfeit Medicines: An Update on Estimates*, WORLD HEALTH ORG. (Nov. 15, 2006), https://www.who.int/medicines/services/counterfeit/impact/TheNewEstimatesCounterfeit.pdf.

[10] *Id.*

[11] Libby Baney & Carmen A. Catizone, *Battling the Epidemic of Illegal Online Drug Sellers and Counterfeit Medicines*, UNITED STATES PHARMACOPEIA: QUALITY MATTERS BLOG (June 30, 2015), https://qualitymatters.usp.org/index.php/battling-epidemic-illegal-online-drug-sellers-and-counterfeit-medicines.

[12] *Id.*

[13] *Fake Drugs Kill Over 700,000 People Every Year—New Report*, INT'L POLICY NETWORK, http://archive.is/ipW8i (last visited Sept. 22, 2016).

Effective tracking and tracing of a medication during its entire supply chain cycle could be an effective tool to solve these problems and has already been widely adopted by the food industry. The booming Internet of Things (IoT) technologies,[14] quick response (QR) codes,[15] and the blockchain technology for supply chains can be used to ensure safety.[16] QR codes, in combination with IoT, make it possible to detect potential safety threats making it possible for a rapid response to deal with such threats. They also create confidence with consumers.

This Article is organized as follows: Section 1 presents the vulnerabilities that exist in the pharmaceutical supply chain, Section 2 discusses the populations that are vulnerable to counterfeit medication, and Section 3 discusses the mechanisms by which counterfeiters target vulnerable populations using platforms like Pinterest. Then, Section 4 highlights the mechanisms that pharmaceutical companies have started to implement and their shortcomings, Section 5 presents potential solutions to the problem by implementing the use of QR codes/IoT and blockchain technology, and Section 6 discusses the benefits the system has for pharmaceutical companies. Section 7 concludes by explaining how the system could help ease the opioid the crisis by highlighting counterfeit controlled substances.

II. Vulnerabilities: The Broken Supply Chain

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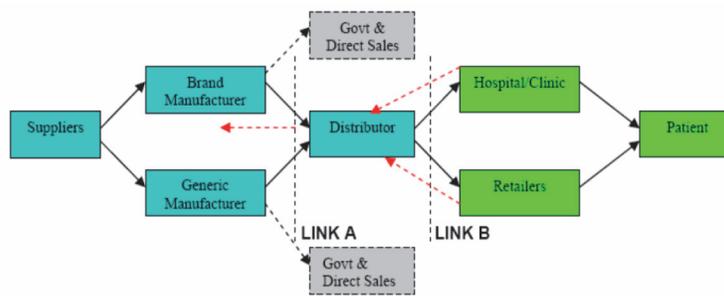
[14] Steve Ranger, *What Is the IoT? Everything You Need to Know About the Internet of Things Right Now*, ZDNET (Aug. 21, 2018), https://www.zdnet.com/article/what-is-the-internet-of-things-everything-you-need-to-know-about-the-iot-right-now/ ("The Internet of Things, or IoT, refers to the billions of physical devices around the world that are now connected to the internet, collecting and sharing data.").

[15] Margaret Rouse, *QR Code (Quick Response Code)*, WHATIS.COM, https://whatis.techtarget.com/definition/QR-code-quick-response-code (last updated Jan. 2013) ("A QR code (quick response code) is a type of 2D bar code that is used to provide easy access to information through a smartphone.").

[16] Justin Evans, Comment, *Curb Your Enthusiasm: The Real Implications of Blockchain in the Legal Industry*, 11 J. BUS. ENTREPRENEURSHIP & L. 273, 275 (2018) (explaining that a blockchain is a continuously growing, virtual distributed ledger comprised of digitally recorded and encrypted, or "cryptographically hashed," data in the form of blocks, with each block cryptographically linked to the previous and/or subsequent block).

The pharmaceutical industry's supply chain can be considered broken in many ways. Many of the American pharmaceutical companies have developed and implemented strong infrastructures protecting domestic supply chains but experience a break down internationally. This break down can be due to the level of sophistication of the vendors and/or suppliers abroad who may not subscribe to the use of technology such as updated computers and the IoT.

Though the United States has one of the safest and most controlled pharmaceutical supply chains, there have been recent situations that would cause doubt amongst consumers. Counterfeit drugs are often manufactured overseas in countries like China, India, Russia, Nigeria, Egypt, and Turkey because of their lack of laws regulating the export of these medications.[17] The United States accounts for less than 1% of the counterfeit drug supply chain. However, it accounts for over 40% of the world's prescription drug sales.[18] As many drug companies are based and have manufacturing plants in the United States, 80% of the active ingredients used in the medications sold in the United States originate from countries that have a high counterfeit issue.[19] These drugs are then distributed to doctor's offices at a steep discount.[20] In 2009, Amed Villa robbed a GlaxoSmithKline Virginia warehouse making off with $13 million in pharmaceuticals. The Eli Lilly burglary included medications for treating psychiatric disorders, cancer, and heart disease. The robbery itself is not the most shocking part, but rather the fact that these stolen medications made their way into 22 pharmacies in Texas.

Additionally, in a separate incident during 2010, the Food and Drug Administration (FDA) was able to track a nonactive form of the cancer drug Avastin to Montana Health Care Solutions, which is owned by a Canadian company who imported the counterfeit medication from Turkey. With a secure supply chain pipeline already in place, how is it that stolen medications were able to make it to the marketplace?

In 2015, a federal court in Ohio found that distributors of counterfeit medications would fake records to create the illusion that the medication looks legitimate to pharmacies. Some of the health care providers looking to make a profit often overlook their patient's safety by selling them counterfeit medications. This is evidenced by reports of doctors knowingly purchasing medication from unlicensed

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[17] INT'L MED. PRODS. ANTI-COUNTERFEITING TASKFORCE, *supra* note 9, at 2–3.

[18] INT'L MED. PRODS. ANTI-COUNTERFEITING TASKFORCE, *supra* note 9.

[19] Memorandum from the Comm. on Energy and Commerce to the Subcomm. on Oversight and Investigations 5 (Feb. 25, 2014) (on file with the U.S. House of Representatives Document Repository), https://docs.house.gov/meetings/IF/IF02/20140227/101804/HHRG-113-IF02-20140227-SD002.pdf.

[20] *Id.*

pharmacies, which often have been found to be counterfeit. McLeod Cancer ordered its oncologic medications from a Canadian business up until 2007, when nurses raised concerns about the medication. A year later, McLeod Cancer was back to ordering the counterfeit medication and billing Medicare for it. Investigators have found that at least 79 United States medical practices have purchased counterfeit medications from foreign or unlicensed pharmacies.[21]

In 2013, President Barack Obama signed a law securing the drug distribution system to help combat the issue of counterfeit medications. The new law required that by 2017, prescription drug packaging include a serial number to allow for tracking of the medication from the manufacturer to the pharmacy or doctor's office. While this is a step in the right direction, it still leaves open the possibility that counterfeiters are able to copy the serial numbers or refill the prescription container with counterfeit medication.

III. VULNERABLE POPULATIONS: THE ELDERLY AND ECONOMICALLY CHALLENGED

Counterfeiters often target vulnerable populations like those on fixed income, such as the elderly, and those in lower socioeconomic classes because they are unable to afford the full price of medications and therefore must turn to alternatives. Counterfeiters target individuals that are over the age of 50 because they account for 71% of all outpatient prescriptions in America. The use of prescription medications by elders has risen by 39% over the last decade.[22] In fact, 40% of the elderly (65 and above) use 5 or more different medications weekly.[23] Patients are often lured into purchasing medication from unlicensed pharmacy websites because of their drug discounts, easy access, and relaxed or non-existent prescription requirements.

With the expansion of internet commerce, many consumers have started to use the internet to complete tasks that range from grocery shopping to car shopping. With this has come a false sense of trust in suppliers, including online pharmacies. Many of these pharmacies are unlicensed, supplying counterfeit medications that originate

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[21] Armen Keteyian, *U.S. Doctors Buying Unapproved Drugs*, CBS NEWS (Dec. 12, 2012, 12:25 PM), https://www.cbsnews.com/news/us-doctors-buying-unapproved-drugs.

[22] COMMUNITY CATALYST, *Protecting Seniors by Ensuring Safe Drug Manufacturing* 1 (2011), https://www.communitycatalyst.org/doc-store/publications/Protecting_Seniors_Ensuring_Safe_Drug Manufacturing.pdf.

[23] Jerry H. Gurwitz, *Polypharmacy: A New Paradigm for Quality Drug Therapy in the Elderly?*, 164 JAMA 1957, 1959 (2004).

in China and India.[24] In a recent survey that asked 6,000 people if they had purchased prescription medications online, 23% confirmed that they had.[25] Of the individuals that have purchased medications online, 20% have admitted to purchasing from sites that were not associated with their insurance or health professional.[26] Because of the rising cost of prescription medication, 44% of those who have purchased medications online admit that they are not associated with a local pharmacy or health insurance plan and rely on other consumer's comments and ratings when deciding to purchase online.[27]

When the National Association of Boards of Pharmacy (NABP) investigated more than 11,000 websites that sell medications, it found that 96% of these sites were out of compliance with regulations established by the FDA.[28] The NABP found that 88% of these sites do not require their customers to have a valid prescription when allowing the purchase of a specific medication.[29] The investigation also revealed that 50% of these sites offer foreign or non-FDA approved medications.[30] Unfortunately, the NABP determined that 62% of these sites sold medication that was counterfeit or substandard. While it is illegal to import foreign medications, the FDA has chosen not to enforce their authority when an individual American citizen imports a small quantity of medication.[31] The cost of medicine has continued to increase and as a result, the Centers for Disease Control and Prevention has reported that over five million Americans import medications for personal use.[32] It has been estimated that in 2014, over 35 million patients were unable to afford their prescription

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[24] U.S. FOOD AND DRUG ADMIN., *Buying Medicines Online? Be Wary, FDA Says* 1, 1 (2012), https://web.archive.org/web/20170209120644/www.fda.gov/downloads/consumers/consumerupdates/ucm321495.pdf (last visited Sept. 17, 2016).

[25] *Id.*

[26] *Id.*

[27] *Id.*

[28] NAT'L ASS'N OF BDS. OF PHARMACY, *Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators* 3 (2015), https://nabp.pharmacy/wp-content/uploads/2016/08/NABPIDOIReportJuly2015.pdf.

[29] *Id.* at 5.

[30] *Id.*

[31] GABRIEL LEVITT, ONLINE PHARMACIES, *Personal Drug Importation and Public Health: Ill-Considered Enforcement Prevents Access to Safe and Affordable Medication* 49 (2015), http://www.pharmacychecker.com/online-pharmacies-personal-drug-importation-public-health.pdf.

[32] *Id.* at 3.

medications.[33] As a result of not being able to afford their medication, over 50% of these patients reported that their conditions worsened.[34]

Studies tracking the trends of counterfeiters have found that these individuals have shifted from Botox and Viagra to more lifesaving drugs like those for cancer, HIV/AIDS, and high cholesterol.[35] This shift by the counterfeiters means they now potentially affect a greater majority of citizens.[36] The harm that these citizens face is that their medications do not contain the appropriate drug and therefore, the patient does not receive the appropriate treatment.[37] This occurs when a prescription container is restocked with the wrong drug, fake medication, or a drug is sold that has become inactive due to expiration or subpar storage.[38] Fake or ineffective medications not only fail to cure a patient but may also contribute to disease progression. This is particularly evident in the case of cancer.[39]

In addition, patients that purchase medication that has expired or has been watered down will be receiving the wrong concentration or dose with the counterfeit medication.[40] This was the case when a physician was sold a research version of Botox that was a stronger dose only intended for research purposes.[41] The use of this medication by the physicians resulted in their patients suffering from respiratory paralysis nearly leading to death.[42]

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[33] SARA R. COLLINS ET AL., *The Commonwealth Fund, the Rise in Health Care Coverage and Affordability Since Health Reform Took Effect* 4 (2015), http://www.commonwealthfund.org/~/media/files/publications/issue-brief/2015/jan/1800_collins_biennial_survey_brief.pdf (accessed Sept. 30, 2016).

[34] USA TODAY, KAISER FAMILY FOUND. & HARVARD SCH. OF PUB. HEALTH, *Health Care Costs Survey* (2005), https://kaiserfamilyfoundation.files.wordpress.com/2013/01/7371.pdf.

[35] Joe Eaton, *Counterfeit Drugs Are Flooding the Nation's Pharmacies and Hospitals*, AARP (May 2016), https://www.aarp.org/health/drugs-supplements/info-2016/counterfeit-prescription-drugs-rx.html.

[36] *Id.*

[37] *Id.*

[38] *Id.*

[39] *Id.*

[40] Daniel S. Chertow et al., *Botulism in 4 Adults Following Cosmetic Injections With an Unlicensed, Highly Concentrated Botulinum Preparation*, 296 JAMA 2476, 2477 (2006).

[41] *Id.*

[42] *Id.*

IV. WHY COUNTERFEITING MEDICATIONS IS THE PERFECT CRIME

When a drug proves to be ineffective, physicians and nurses alike do not normally suspect that the etiology could be a counterfeit medication that was prescribed to the patient, but rather a poor clinical outcome that is due to human variation.[43] Often the patient is also not aware that he/she is taking a counterfeit medication until it is too late.[44] Physicians traditionally do not inquire into where their patients purchase the medication that they have prescribed them, and patients are often embarrassed to disclose that the medication was purchased online from an unlicensed site.[45] When a conflict arises, it is often difficult to reference the medication package as it is typically discarded after use. The pills themselves often present an issue for retrospective referencing, as they are generally metabolized by the patient's body. "Consequently, no one suspects, no one tells, and any evidence is discarded or digested."[46] This collectively results in difficulty in properly investigating forensically where, how, and what happened when the patient took the counterfeit medication.[47]

V. HOW COUNTERFEITERS TARGET VULNERABLE POPULATIONS

A 2018 report published by the NABP revealed that counterfeiters employ social media sites to redirect vulnerable populations to rogue pharmacy sites.[48] NABP conducted a four-week study in which it performed key word searches on multiple social media platforms and discovered that multiple social media pages had advertisements leading to rogue pharmacy sites. These rogue sites were selling commonly counterfeited prescription medications.[49] For example, NABP found 66 sites on Pinterest that were promoting medication, 38% of which were selling

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[43] *Father Was Told Dying Daughter Was Fine After Illegal Vaccination*, RADIO FREE ASIA (June 29, 2005), https://www.rfa.org/english/china/china_vaccinations-20050629.html.

[44] *Id.*

[45] *Id.*

[46] *Doctors Involved in Spreading of Fake Drugs*, SUN STAR (PHILIPPINES) (Aug. 21, 2005), http://www.sunstar.com.ph/static/pan/2005/08/21/news/12.doctors.involved.in.spreading.of.fake.drugs.health.office.html.

[47] *Id.*

[48] *Social Media Sites: The New Wild West for Illegal Online Pharmacies*, NAT'L ASS'N OF BDS. OF PHARMACY (Oct. 1, 2018), https://nabp.pharmacy/social-media-sites-the-new-wild-west-for-illegal-online-pharmacies.

[49] *Id.*

medication illegally.[50] The agency has searched for commonly counterfeited lifestyle medications on Instagram, Facebook, Twitter, Reddit, and eBay, and it has also found that 95% of rogue medication sales websites sell prescription drugs illegally.[51] Fortunately, Snapchat and Twitter require individuals that are advertising pharmacies and pharmaceutical products to first be verified by the agency.[52]

VI. POTENTIAL SOLUTIONS

A.   The Current System

Today, there are a number of track and trace applications that pharmaceutical companies employ for the monitoring of their medication. This includes the use of serial bar codes and RFID tagging.[53] Pharmaceutical companies use these tactics with the hope that they are able to track and stop counterfeit medication from entering their supply chain.[54] During the manufacturing process, a unique identity is added to each stock unit and remains with it through the supply chain.[55] The theory is that a patient would be able to use their cell phone to text the unique serial number on the medication to a centralized entity that would then help to verify the legitimacy of the drug.[56] The legitimacy of the drug would be verified based on the prior search history so if that serial number had been searched before, the customer would know that it is counterfeit.[57] However, if the medication has not been searched before then in theory the drug is authentic.[58] The issue with this method is that it assumes that those counterfeiters do not have access to the centralized server. The system also relies on the ability of elderly, dyslexic, and foreign individuals to put the correct number into the system. What if a counterfeit medication is identified as legit, but is indeed false because a hacker or internal personnel was able to input new serial

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[50] *Id.*

[51] *Id.*

[52] *Id.*

[53] Claire Swedberg, *RFID Tracks Specialty Drugs Through Pharmaceutical Network*, RFID J. (Aug. 29, 2018), https://www.rfidjournal.com/articles/pdf?17782.

[54] *Id.*

[55] *Id.*

[56] Alberto Coustasse et al., *Could the Pharmaceutical Industry Benefit from Full-Scale Adoption of Radio-Frequency Identification (RFID) Technology with New Regulations?*, 13 PERSP. HEALTH INFO. MGMT. 1 (2016).

[57] *Id.*

[58] *Id.*

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numbers? The current use of serial codes also relies on problematic issues such as the visibility and sizing on varying package labeling.

The current method of detection often relies on customs and pharmacy employees being able to distinguish a well-made counterfeit from the original. With the recent advancements in technology, counterfeiters now have the ability to use systems that convert the counterfeit item into a 3D representation of the original making it even more difficult for detection.[59] To solve these issues, many pharmaceutical companies have added visible security features to their packaging.[60] These security features often include holograms, special ink, and embossing.[61] To further enhance their security, many pharmaceutical companies have been experimenting with employing the use of ink that is invisible to the naked eye.[62] These methods allow for easy identification of counterfeits, but also requires that the pattern or code remain a secret from potential counterfeiters because once it is known, it will be reproduced rather quickly.[63]

B. Revising Status Quo

The Obama Administration implemented legislation that now requires pharmaceutical companies to include a serial number on prescription drug packaging to enable tracking of medication from the manufacturer to the pharmacy or doctor's office.[64] A potential solution is to create an app that allows for a consumer to enter the serial number from the packaging to verify that their medication came, for example, from Bayer's manufacturing plant to the CVS drugstore, where they would like to purchase it. As a great step in the direction of transparency, this regulation is expected to tighten up and standardize the pharmaceutical supply chain by making it more difficult for counterfeit medications to enter it. If counterfeits actually are able to infiltrate the supply chain, it helps authorities identify the potential entry point.

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[59] Robert Service, *You could soon be manufacturing your own drugs—thanks to 3D printing*, SCI. (Jan. 18, 2018), http://www.sciencemag.org/news/2018/01/you-could-soon-be-manufacturing-your-own-drugs-thanks-3d-printing.

[60] Dipika Bansal et al., *Anti-Counterfeit Technologies: A Pharmaceutical Industry Perspective*, SCI PHARM 81(1):1–13 (Jan.–Mar. 2013).

[61] *Id.*

[62] *Id.*

[63] *Id.*

[64] Erich D. Brechtelsbauer et al., *Review of the 2015 Drug Supply Chain Security Act*, HOSP PHARM 51(6): 493–500 (June 2016).

The method being proposed by the industry is a track and trace system that uses the ePedigree technology or 2D barcodes.[65] The system uses randomized serial numbers on each package of medication.[66] The authenticity of each medication is verified by entering the serial number located on the package into a repository system that was entered at the point of manufacturing.[67] This can allow for verification at each point of the supply chain.[68] The system is only effective if the supply chain of that medication is verified before being sold to patients. The issue with this system is that, as mentioned above, some pharmacies and doctors' offices have been found to circumvent purchasing legitimate medications.

Even before reaching the patient, medications travel through a vast network of retailers, distributors, transporters, storage facilities, and suppliers that participate in manufacturing, delivery, and sales, yet the journey of the medication remains an unseen dimension to the end consumer. There is a growing effort by the FDA's Division of Supply Chain Integrity "to reduce threats to the global drug supply chain through increased transparency and accountability, effective enforcement, and promotion of proactive industry vigilance and voluntary compliance."[69] When pharmaceuticals retain the full chains of custody, it makes it rudimentary and difficult to verify.[70]

Verification of the authenticity of the medication should be placed in the hands of consumers.[71] No single organization should be trusted to monitor all of its medication data for the supply chain.[72] Relying on a single entity allows for a single point of weakness that is vulnerable to bribery, social engineering, and other forms of hacking.[73] Currently, access to the repository system would stop with the pharmacies, but Blockchain creates a unique opportunity for the healthcare industry to provide transparency for its consumers. Blockchain has the ability to serve as the

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[65] Renee Bassett, *E-Pedigree: How Automation Secures the Pharmaceutical Supply Chain*, AUTOMATION WORLD (Sept. 24, 2013), https://www.automationworld.com/article/technologies/vision/e-pedigree-how-automation-secures-pharmaceutical-supply-chain.

[66] *Id.*

[67] *Id.*

[68] *Id.*

[69] Division of Supply Chain Integrity, U.S. Food & Drug Admin., https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm348584.htm (last updated May 2, 2017).

[70] *Id.*

[71] *Id.*

[72] *Id.*

[73] *Id.*

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repository for all of the points in the pharmaceutical supply chain. If the supply chain data was gathered and verified by third parties, it allows for the data being monitored to be unbiased.

VII. WHAT IS SUPPLY CHAIN ON BLOCKCHAIN?

Pharmaceutical supply chain refers to the process of medication production, processing, transportation, distribution, to consumption and disposal of expired goods. Traceability in the pharmaceutical industry is critical for its revenue and corporate compliance.[74] Traceability allows pharmaceutical companies to locate a lot of individual medication and follow its history in the supply chain from manufacturer to consumer.[75] Traceability is a mandatory requirement for compliance with many government entities, increasing security and the confidence for patients.[76] With the emergence of new technologies like IoT and Blockchain technologies, technology has the potential to create transparency for a complex supply chain.[77] This can be accomplished by storing the cryptographic hashes of each individual device firmware onto the blockchain.[78] The blockchain will create a permanent record of device configuration and state.[79] Storage of the records on the blockchain "can be used to verify that a given device is genuine and that its software and settings have not been tampered with or breached."[80] Tools like IoT sensors have the capacity to provide real-time data on location and timestamps throughout the supply chain.[81]

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[74] THE KAISER FAMILY FOUND., *supra* note 5.

[75] Henry M. Kim & Marek Lasakowski, Towards an Ontology-Driven Blockchain Design for Supply Chain Provenance (Mar. 2018) (unpublished manuscript) (on file with Wiley Online Library).

[76] *Id.*

[77] Amit Chourey, *5 ways IoT can digitally transform pharma supply chain*, LINKEDIN (Feb. 22, 2017), https://www.linkedin.com/pulse/5-ways-iot-can-digitally-transform-pharma-supply-chain-amit-chourey.

[78] Shermin Voshmgir & Valentin Kalinov, *Crytography & Blockchain—Part 2*, BLOCKCHAINHUB (Sept. 10, 2018), https://blockchainhub.net/blog/blog/cryptography-blockchain-bitcoin (Cryptographic hashing is a mathematical method for transforming large amounts of data into a unique string of text that are difficult to imitate. Any piece of data can be hashed, no matter its size or type. A hash is designed to act as a one-way function—you can put data into a hashing algorithm and get a unique string, but if you come upon a new hash, you cannot decipher the input data it represents.).

[79] Evans, *supra* note 16.

[80] Nir Kshetri, *Can Blockchain Strengthen the Internet of Things?*, 19 IT PROF'L 68 (Aug. 2017), http://libres.uncg.edu/ir/uncg/f/N_Kshetri_Can_2017.pdf.

[81] Justin Evans, *Contracting for a Connected World*, INTELLECTUALLY JAY (Oct. 18, 2018), https://www.intellectuallyjay.com/2018/10/contracting-connected-world/.

This technology would increase data integrity, making it nearly impossible for counterfeiters to tamper with the records of the medication.

The blockchain, serving as a shared database, offers highly secure and immutable access to the supply chain.[82] A blockchain is a decentralized virtual ledger of transactions that are distributed amongst a network of computers (nodes).[83] There is not a single computer that governs the data being added to the blockchain.[84] For a transaction to be uploaded to the blockchain, there must be a consensus of nodes on that blockchain which would have to mathematically verify the transaction.[85] Before information can be verified by the other nodes on the blockchain, the author of the data must be authenticated.[86] Authors are authenticated by their digital signature, a cryptographic mechanism that is similar to a physical signature but is more secure.[87] Digital signatures also enable a party to prove their identity for each transaction without the worries of being impersonated.[88] The requirement of a digital key prevents parties within the company from adding information to the blockchain unless the worker has access to the digital key.[89] The blockchain is ideal for monitoring and tracking because unlike traditional systems, which often have heterogeneous types of data being inputted from various sources, it stores information based on each digital signature used for each interaction.[90] The use of a digital key makes it possible to verify and audit the actions of others within the blockchain.[91]

Blockchain offers pharmaceutical companies, health care providers, distributors, and pharmacies an inter-organizational recordkeeping platform, multiparty aggregation storage for a large number of sources, and provenance tracking.[92] Each of the participants in a protected supply chain will be assigned

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[82] Evans, *supra* note 16.

[83] *Id.*

[84] *Id.*

[85] *Id.*

[86] *Id.*

[87] *Id.*

[88] Justin Evans, *Blockchain Can Revolutionize the Patenting of Inventions?*, INTELLECTUALLY JAY (Apr. 15, 2017), https://www.intellectuallyjay.com/2017/04/blockchain-can-revolutionize-patenting-inventions.html.

[89] Evans, *supra* note 16.

[90] *Id.*

[91] *Id.*

[92] Kim & Lasakowski, *supra* note 75.

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registration of a unique digital identity, linking their actual identity with their blockchain-based digital identity allowing for them to interact on the blockchain as they complete their role in the supply chain.[93]

In order for data that is uploaded to the blockchain to be understood by all parties, there must be a common interpretation of the data. Because of the immutability of the blockchain, each party that is looking at the blockchain will be able to see the original data stored on the blockchain by the manufacturer, which cannot be altered.[94] This means that blockchain reduces fraud and errors, reduces delays from paperwork, identifies issues faster, and increases consumer and partner trust. The trust that currently exists is based on the reputation of the pharmacy or pharmaceutical company.

Using blockchain to maintain a pharmaceutical company's supply chain can make it possible to contain an IoT security breach in a systematic manner when there is the discovery of a breach. The pharmaceutical company would be able to pinpoint when the counterfeited medications enters the supply chain. Blockchain can assist in the facilitation of handling and dealing with instances such as recalls due to security vulnerabilities. The transparency of blockchain makes it possible for the company to trace back every product to the origin of the raw materials, and transactions can be linked to the identity of the source. IoT-linked security crises, such as stolen medication, can be linked to the source instantly which allows for the company to then notify the authorities instantly. Indeed, notification of authorities could be programmed into the blockchain if each party uses a smart contract. Smart contracts are self-executing electronic contracts that are coded on the blockchain between members of the blockchain community. Smart contracts are an automated computer process that is coded to receive inputs from both parties and facilitates and to verify or enforce the negotiation or performance of that contract as defined by predetermined instructions.

The pharmaceutical company could have the notification come to a member of the company to verify the breach before notifying the authorities. The use of the smart contract will allow for each duty defined in the contract to be verified by an IoT device, therefore triggering non-performance by either party. This allows for the pharmaceutical company to monitor the performance of each vendor associated with its supply chain. The instant notification of the breach allows the pharmaceutical company to confine the incident before it enters the market. The use of the blockchain by consumers will also allow the pharmaceutical company to contain counterfeit medications by giving consumers the ability to notify the company when it purchases counterfeit medications. Consumers would be able to detect counterfeit

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[93] *Id.*

[94] Evans, *supra* note 16.

medication by scanning each prescription's QR code, which is then linked back to the blockchain of the pharmaceutical company.

VIII. QR Code Provenance

The QR code has become widely adopted in the food supply chain due to its faster readability, larger storage capacity, and cost.[95] QR coding prescription medication can be a powerful authentication method for pharmaceutical companies.[96] QR code is a 2D matrix code that contains information in a vertical and horizontal direction and has a low level of error corrections.[97] QR coding makes it difficult for counterfeiters to copy or replace the code, whereas the current method of applying serial numbers to the packaging of medications can be easily duplicated.[98] QR codes allow for the storage information or data for the identification and tracking for monitoring of drugs authenticity.[99] A scanner such as a smartphone with a QR code scanner app can be used to access this information.[100]

QR codes that are printed directly onto the medication are then linked to a private blockchain owned by the pharmaceutical company. This allows consumers to verify the authenticity of the drug; a patient can do a quick scan to get information on the pharmaceutical drug's supply chain. By scanning the medication, the patient will not only see the supply chain, but it will also reveal medical information about the medication itself. This could help ensure that an individual is not taking the wrong medication or medication from outside of the pharmaceutical company's supply chain.

The use of QR codes also allows for the pharmaceutical company to detect the point of entrance for counterfeit drugs, allowing for the pharmaceutical companies to react in a timely manner to prevent it from reaching their consumers.[101] If the pharmaceutical company does not respond fast enough, QR codes put power in the hands of consumers by allowing them to know in real time if the medication is

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[95] Amarjeet Mundi, *Provenance: Vehicle Maintenance with QR Code Based Blockchain and Weather*, IBM Developerworks Recipes (Aug. 15, 2017), https://developer.ibm.com/recipes/tutorials/provenance-vehicle-maintenance-with-qr-code-based-blockchain-and-weather/.

[96] *Id.*

[97] *Id.*

[98] *Id.*

[99] Project Provenance Ltd., *Blockchain: The Solution for Transparency in Product Supply Chains*, Provenance (Nov. 21, 2015), https://www.provenance.org/whitepaper.

[100] *Id.*

[101] *Id.*

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counterfeit. Pharmaceutical companies and/or government agencies can now start a reporting program for consumers who purchase counterfeit medications to notify others of the websites and social media pages that they purchased from. This information can be critical for providing the evidence that is needed to remove a social media posting or website or at least provide advisory notification.

IX. CONTRACTING WITH THE PHARMACEUTICAL COMPANY

Smart phones have evolved dramatically over the past few years and have increased in functionality and computing power.[102] One of the most notable advancements has occurred in a smart phone's imaging and video capability.[103] Smart phones, therefore, have the ability to be used for digital authentication on the fly for the detection of counterfeit medication.[104] The ideal scenario that would best address counterfeit medication would utilize smart contracting with the consumer and pharmaceutical company.[105] The consumer would go online and order their medication directly from the pharmaceutical company, thereby creating a smart contract with the company. Similar to when you order pizza from Dominos, the consumer would have access to each important step in the supply chain, up to delivery to their door.[106] This creates confidence with the consumer that their medication is genuine. In situations where the consumer is ordering medication from a doctor's office or pharmacy, the consumer would be added as an additional step to the supply chain. This allows the consumer to see where the drug has been before it was in their possession. The aim of smart contracting is to create transparency by documenting provenance.

The use of QR codes and smart phone apps also allows the pharmaceutical company to get feedback from customers, regarding the effectiveness, content, and other subjective evaluations for the medication.[107] This information is essential for

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[102] Cory Protin, *Here's How Drastically Cell Phones Have Changed Over the Past 40 Years*, BUS. INSIDER, (July 27, 2017, 8:06 AM), https://www.businessinsider.com/cell-phone-history-cars-mobile-motorola-apple-bell-labs-samsung-google-2017-7.

[103] *Id.*

[104] *Id.*

[105] *Id.*

[106] Katherine Bindley, *Domino's Tracking App Tells You Who Made Your Pizza—Or Does It?*, WALL ST. J. (Nov. 28, 2017, 12:17 PM), https://www.wsj.com/articles/dominos-tracking-app-tells-you-who-made-your-pizzaor-does-it-1511889445.

[107] Sangkwon Han et al., *Drug Authentication using High Capacity and Error-Correctable Encoded Microtaggants*, DEPT. OF ELECTRICAL ENGINEERING & COMPUTER SCIENCE, INTER-UNIVERSITY SEMICONDUCTOR RESEARCH CTR., SEOUL NAT'L UNIV. (Oct. 28, 2012), http://www.rsc.org/images/loc/2012/pdf/T.9.198.pdf.

the pharmaceutical company's quality control and compliance programs. As previously mentioned, it allows for warning information for potential problems. If a single QR code appears in more than one location, the pharmaceutical company can reach out to the consumers instantly to recall the medication due to potential counterfeit issues. The pharmaceutical company would be able to step in quickly to ensure that the patient does not continue on the counterfeit, allowing the patient to go untreated.

Government agencies are still trying to determine the level of impact from the sale of Avastin that lacked an active ingredient which patients needed to survive.[108] The FDA found that nineteen clinics in California, Texas, and Illinois purchased the counterfeit version of the drug from Montana Health Care Solutions.[109] The drugs appear genuine to physicians as they were labeled with the drug's name and the manufacturer but did not contain Avastin, nor a generic, or the same active ingredient.[110] There are only eight distributors that are authorized to sell Avastin to hospitals and doctor offices, but Montana Health Care Solutions was not listed as one.[111] If the patients or physicians were able to see the supply chain of the drug, they would have realized that the drug did not lead back to the manufacturer, Roche.

X. CAN THE QR-CODE/BLOCKCHAIN BE THE ANSWER TO THE OPIOID COUNTERFEIT CRISIS

The number of Americans that are dying from opioids has increased dramatically in recent years, and legislatures are scrambling to find solutions to fix the situation. Fentanyl, a synthetic opioid, is often prescribed to patients to treat severe pain.[112] Counterfeit fentanyl is being manufactured in countries like China and imported into America. U.S. law enforcement is finding an increased number of fentanyl-laced medications, as well as street drugs, that resemble the authentic version of the medication. The NABP found in its recent publication that 40% of online sites that sell controlled substances, which includes opioids that are frequently

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[108] Katie Moisse, *Cancer Patients Furious Over Counterfeit Avastin*, ABC NEWS (Feb. 15, 2012), https://abcnews.go.com/Health/CancerPreventionAndTreatment/cancer-patients-furious-counterfeit-avastin/story?id=15629540.

[109] *Id.*

[110] *Id.*

[111] *Id.*

[112] Drug Enforcement Admin., DEA Report: Counterfeit Prescription Pills Containing Fentanyls: A Global Threat (July 22, 2016), https://www.dea.gov/press-releases/2016/07/22/dea-report-counterfeit-pills-fueling-us-fentanyl-and-opioid-crisis.

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linked to fentanyl-related to overdoses.[113] In fact, the most popular controlled substance sold on these sites was Xanax, which counterfeit often contains fentanyl.[114] Counterfeit fentanyl has been linked to an increase in seizures and deaths, resulting in more than 49,068 American deaths in 2017 alone.[115] Of these deaths, 66% were caused by opioids, including fentanyl.[116]

The use of blockchain will give distributors the ability to do their due diligence on licensed pharmacies, hospitals, and other dispensaries who are looking to purchase controlled substances. The transparency of the blockchain allows for vetting the purchaser by internal and external experts before granting permission to ship. The transparency of the blockchain also allows for the employment of sophisticated technology, like Libra, that monitors the ordering of controlled substances.[117] If any entity exceeds the allotted recommendations, the program alerts the other points up stream of the pharmacy or hospital for further analysis and possible cancellation. Information on the blockchain is timestamped, which allows for entities to assemble daily reports of all opioid medication orders for the FDA with ease. The blockchain reports would contain the hash used by each entity, which could be assigned in a private blockchain; the quantity of opioid medication for each hash; and the type of opioid medication purchased by each hash. If a pharmaceutical company decides to use a private blockchain for its supply chain, it could assign a unique hash for each licensed pharmacy, hospital, or other dispensary. Assigning a unique hash allows for the owner of the blockchain, the pharmaceutical company, to ensure that all of the downstream customers are licensed by regulatory agencies or patients with accurate prescriptions. These measures will help pharmaceutical companies and other points in the supply chain from sending thousands of suspicious orders to entities that are not licensed or that are licensed but are abusing their authority.

XI. CONCLUSIONS

Counterfeit medications are an issue that government entities and pharmaceutical companies must address to help protect their citizens and consumers. The driving force for the change in laws and the procedures implemented by

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[113] NAT'L ASS'N OF BDS. OF PHARMACY, *supra* note 28.

[114] *Id.*

[115] *Overdose Death Rates*, NAT'L INST. ON DRUG ABUSE, https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates (last updated Aug. 2018).

[116] *Id.*

[117] *About Libra*, LIBRA. TECH (2019), (https://libra.tech/about) (Libra, a blockchain application, provides a system of record that automates and optimizes accounting, audit and tax processes for funds, fund administrators, exchanges, trading operations and enterprises.).

government entities and pharmaceutical companies will be the opioid crisis. With the deaths of patients who have purchased counterfeit opioids ranging in the tens of thousands, the new era of drug distribution compliance will alter the way the pharmaceutical supply chain functions for the better. Without placing the power in the consumer's hands, the new procedures will not tackle the problem of counterfeit drugs completely because of access to unlicensed pharmacies and the internet. There is a need to make track and trace technology a global standard for the pharmaceutical supply chain to ensure the safety of the consumers.

Real-time tracking and tracing of medication will help to ensure the safety and quality of medication in the pharmaceutical supply chain. The use of QR code, IoT technologies, and blockchain technology proposed in this paper will help to create a platform for integrated tracking and tracing for medication. QR codes can be imbedded on each pill, highlighting its journey and critical medication information from the pharmaceutical company. The technical architecture of an IoT-based blockchain tracking and tracing platform allows not only for item level tracking of each pill but also for the entire journey of the medication in the pharmaceutical supply chain to be known in real-time. The use of the blockchain platform enables information sharing among all of the involved parties along the pharmaceutical supply chain allowing full transparency for issues that arise during the journey to the consumer. Finally, the transparency provided by the blockchain could identify responsible parties when safety incidents happen, facilitating timely responses to protect consumer health, in situations such as the opioid crisis.

Implementation of a blockchain system for pharmaceuticals will require all of the parties involved in the pharmaceutical supply chain. First, the scalability and compatibility of the QR code, IoT, and blockchain should be further evaluated in more real-life cases as it has been in the food supply chain. Second, the blockchain data analytics tools should be further explored to support the operational optimization during the pharmaceutical supply chain. Finally, an effective warning system should also be developed. Doing so will protect consumers and decrease the likelihood of tragedies like the opioid crisis.