BLOCKCHAIN FOR DSCSA COMPLIANCE

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I. INTRODUCTION

As the pharmaceutical supply chain continues to expand globally, issues with substandard drugs pose a growing problem for the US pharmaceutical industry. Counterfeit drugs and diverted drugs are two significant problems in the pharmaceutical supply chain that stem in part from inadequate tracking and tracing of the drug. Traditional methods such as holograms, unique watermarks, tamper-proof packaging, and color changing inks are currently being used to help secure the supply chain against counterfeit

drugs and drug diversion.[1] While these methods provide improved security, making it more difficult to counterfeit a drug, they fail to adequately address the major underlying problem of tracking a drug's pedigree from manufacturer to consumer and everywhere in between.

The World Health Organization has estimated that 10% of drugs in the global market are counterfeit.[2] Since 2000, every single state in the US has experienced an incident with counterfeit drugs.[3] There are a variety of dangers that patients face as a result of counterfeit drugs. For example, the counterfeit drug may contain no active ingredient, it may contain no active ingredient combined with harmful ingredients, it may contain an entirely wrong active ingredient, or the drug may contain the wrong concentration or an incorrect dose of the correct active ingredient.[4] In any of these scenarios, patients face serious health risks, whether it be receiving no actual medicine, taking the wrong medicine, or receiving a potentially dangerous incorrect dosage. The dangers counterfeit drugs present are exemplified when over five-hundred children

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[1] Susannah Patton, *Cracks in the Pharmaceutical Supply Chain*, Cambridge Innovation Institute, http://www.bio-itworld.com/newsitems/2006/january/11-18-06-news-supply-chain/.
[2] Bill Berkot, *Fake Avastin shows little protection of drug supply*, Reuters (Mar. 12, 2012), https://www.reuters.com/article/us-avastin-drug-fake/fake-avastin-shows-little-protection-of-drug-supply-idUSBRE82B0YY20120312.
[3] The Partnership for Safe Medicines, *Counterfeit Drugs in America: Crimes, Victims & Solutions*, Fact Pack, 2nd Edition (Mar. 2017), http://www.safemedicines.org/wp-content/uploads/Fact-Pack-2017-web-copy.pdf.
[4] Erwin A. Blackstone, Joseph P. Fuhr Jr. & Steve Pociask, *The Health and Economic Effects of Counterfeit Drugs*, Am. Health & Drug Benefits (June 2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4105729/#R11.

across the globe died of counterfeit cough medicine that was tainted with antifreeze.[5] In recent years, deaths from counterfeit drugs containing the potent ingredient fentanyl have frequently appeared in news headlines stemming from America's opioid crisis. Fentanyl has been found in counterfeit versions of popular opiates such as oxycodone and hydrocodone, as well as counterfeit Xanax. These counterfeits have been found in 44 states and have caused deaths in 26 of those states. [6]

Drug diversion, like counterfeit drugs, is a serious problem in the pharmaceutical supply chain. A diverted drug is one which has "been removed from the regulated distribution channels but then reintroduced into the wholesale marketplace through various means."[7] Drugs are often reintroduced into the legitimate market through the creation of a false drug pedigree. This false pedigree is a falsified history of the drug's path through the pharmaceutical supply chain that conceals the fact that the drug ever left the market, thus making the drug appear as if it came from a legitimate source.[8] Drug diverters repurchase pharmaceuticals that have been dispensed to patients at a discounted price, repackage the drugs,

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[5] Liang BA, *Fade to black: importation and counterfeit drugs*, Am. J. Law Med. 2006; 32: 279–323.
[6] *Fatal Doses of Fentanyl Increasingly Found in Counterfeit Medications*, Partnership for Drug-Free Kids (Oct. 11, 2018), https://drugfree.org/learn/drug-and-alcohol-news/fatal-doses-of-fentanyl-increasingly-found-in-counterfeit-medications/.
[7] U.S. v. Charles Jeffrey Edwards (Counts 1 - 28), Brenda Elise Edwards (Counts 1-27), Jerrod Nichols Smith (Counts 1-16; Count 28)., 2013 WL 12210003 (M.D. Tenn.).
[8] *See* Id.

and then resell the product into the wholesale pharmaceutical market.[9] Drug diversion poses similar risks as counterfeit drugs, as diverted drugs may be expired, stored in improper conditions, or adulterated in some way that causes the drug to lose its potency or become dangerous.[10]

Part I of this Note will illustrate the problems posed by drug counterfeiting and drug diversion, describe current solutions being used to address these problems, and conclude with a discussion of federal legislation that seeks to fix these weaknesses in the pharmaceutical supply chain, focusing on the tracking and tracing requirements that the DSCSA imposes on supply chain participants. In Part II, this Note will examine the development of blockchain technology as well as examine its defining characteristics. Part III will explore current industry efforts to apply blockchain technology to supply chain uses and contends that blockchain is uniquely fit to meet the DSCSA tracking and tracing requirements and fix the weak points in the global pharmaceutical supply chain that allow counterfeit or diverted drugs to enter into the legitimate wholesale market. This Note concludes with a recommendation that the Federal Drug Administration (FDA) continue to monitor industry progress and make accommodations necessary with regard to enforcement of

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[9] *See* Id.
[10] *See* Id.

DSCSA requirements, including potentially extending its deadline for compliance, so as to ensure that members of the pharmaceutical industry have appropriate time to properly develop and implement the best possible supply chain solution, solutions that will likely rely on blockchain technology at some point in the future.

II. BACKGROUND

The US has one of the safest drug supply chains in the world; however, our system is not impenetrable.[11] While this Note is primarily concerned with issues involving counterfeit and diverted drugs, these are just two examples of a broader problem of contaminated, expired, adulterated, or otherwise substandard drugs that are entering the US market as a result of flaws in the supply chain. Drug counterfeiting and drug diversion are both ultimately a result of a failure to track and trace a drug from manufacturer, to repackager, to wholesale distributor, to dispenser. Medications are currently tracked and traced through the supply chain through the use of drug pedigrees that the seller provides to the buyer of a medication.[12] A drug pedigree is, "a statement of origin that identifies each prior sale, purchase, or trade of a drug, including the date of those transactions and the names and addresses of all

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[11] FOOD AND DRUG ADMIN., DRUG SUPPLY CHAIN INTEGRITY, (Oct. 22, 2018), https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/default.htm.

[12] FOOD AND DRUG ADMIN., CPG SEC. 160.900 PRESCRIPTION DRUG MARKETING ACT -- PEDIGREE REQUIREMENTS UNDER 21 CFR PART 203. SECTION 503(E)(1)(A) OF PDMA, (Mar. 6, 2015), https://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm073857.htm.

parties to them."[13] Maintaining secure and accurate drug pedigrees is essential to protecting the US as well as the global supply chain against counterfeit and diverted drugs. Currently drug pedigrees are typically kept as paper or electronic documents, which are susceptible fraud or forgery as evidenced by the multitude of counterfeit and diverted drug incidents. These forged or fraudulent drug pedigrees, known as false drug pedigrees, are created by parties to obscure the actual origins of the drug they are selling. The cases explored in this section highlight how the creation of false drug pedigrees allows for the introduction of counterfeit medication and diverted drugs into the legitimate market.

A. COUNTERFEIT MEDICINE

In 2018 a group of Canadian pharmaceutical companies were convicted of selling counterfeit and misbranded medication throughout the United States.[14] The group of companies including Canada Drugs and its subsidiaries, Rockley Ventures and River East Supplies, was ordered to surrender $29 million in proceeds and to pay a $5 million fine.[15] The FDA found that Canada Drugs was selling unapproved drugs that were labelled with foreign

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[13] *Id.*
[14] U.S. ATTORNEY'S OFFICE DISTRICT OF MONTANA, CANADIAN DRUG FIRM ADMITS SELLING COUNTERFEIT AND MISBRANDED PRESCRIPTION DRUGS THROUGHOUT THE UNITED STATES, (Apr. 13, 2018), https://www.justice.gov/usao-mt/pr/canadian-drug-firm-admits-selling-counterfeit-and-misbranded-prescription-drugs.
[15] *Id.*

languages and had inadequate instructions for use.[16] In order to sell these unapproved and misbranded drugs to US buyers, Canada Drugs purchased other pharmaceutical companies, using the companies' established brand names, drug inventories, and list of customers essentially as shell companies to distribute their product.[17] The U.S. Attorney's Office for the District of Montana stated, "[i]n order to avoid detection, Canada Drugs and its affiliated companies falsified customs forms concerning the value of the drugs shipped into the United States."[18] Canada drugs utilized one such subsidiary company, River East Supplies, to sell counterfeit cancer drugs, Avastin and its Turkish counterpart-drug Altuzan, in the United States.[19] Laboratory testing revealed that these counterfeit cancer drugs had no active ingredient.[20] This is particularly dangerous as the cancer patients taking the counterfeit medication were receiving no benefit from the medication. This creates the risk that upon observing that the counterfeit cancer medicine is not working as expected, unknowing doctors may prescribe a different course of treatment, ultimately depriving the patient of the benefits that the legitimate drug may have provided.

Canada Drugs' counterfeit drug operation highlights weakness in the current regulation of the pharmaceutical supply

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[16] *Id.*
[17] *Id.*
[18] *Id.*
[19] *Id.*
[20] *Id.*

chain. By using subsidiary companies with established business relationships in the United States and by creating false drug pedigrees, Canada Drugs was able to circumvent the protections provided by the regulatory system and introduce counterfeit drugs into the legitimate market. With a secure, accurate drug pedigree that traces each drug from the distributor back to its manufacturer, Canada Drugs' illegal operation would most likely not have been possible. Part C of this Note explores legislative initiatives designed to create a better system for protecting against false drug pedigrees such as the ones utilized by Canada Drugs.

B. DRUG DIVERSION

A recent drug diversion operation centered around a warehouse in Nashville, Tennessee illuminates the flaws in the supply chain that allow for drug diversion and drug counterfeiting. In 2013, three individuals who ran and operated Cumberland Distribution, Inc. ("Cumberland") were indicted and charged with diverting over $50 million of HIV/AIDS, anti-psychotic, anti-depressant, blood pressure, diabetes, and other medications.[21] The United States District Court for the Middle District of Tennessee found that Cumberland was engaged in a street diversion scheme, in which the company purchased various drugs off of the black market, created false drug pedigrees, and resold the medication

[21] U.S. v. Charles Jeffrey Edwards (Counts 1 - 28), Brenda Elise Edwards (Counts 1-27), Jerrod Nichols Smith (Counts 1-16; Count 28)., 2013 WL 12210003 (M.D. Tenn.).

into the legitimate market.[22] From 2006 to 2009, Cumberland purchased millions of dollars worth of medication from unlicensed street suppliers based in New York City and Miami who had previously purchased the drugs from patients in the surrounding areas.[23] After purchasing the drugs from the street suppliers, many of the drugs were shipped to a warehouse in Nashville where they were repackaged to look as if they were newly manufactured drugs.[24] The repackaged drugs were then shipped from the Nashville warehouse directly to pharmacies around the country.[25]

Cumberland also shipped many of the drugs it purchased on the black market to shell companies that it operated in Arkansas and Louisiana.[26] These companies, which were licensed to sell medications, created false drug pedigrees showing that the shell companies had purchased the drugs from legitimate, licensed, drug wholesalers, thus hiding the fact that the drugs were actually sourced from the street suppliers.[27] The drugs were then shipped to the Nashville warehouse where they were repackaged and shipped, along with their seemingly legitimate false drug pedigrees, to pharmacies across the country.[28]

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[22] *Id.*
[23] *Id.*
[24] *Id.*
[25] *Id.*
[26] *Id.*
[27] *Id.*
[28] *Id.*

The Cumberland case illustrates the dangers of drug diversion, as unknowing pharmacies that purchased the drugs from Cumberland reported various problems with the drugs. These problems included bottles that contained the wrong medicine, wrong dosage information, and shockingly, even some bottles that contained breath mints instead of medicine. If it were not for the false drug pedigrees that Cumberland provided to the dispensing pharmacies, the pharmacies could have entirely avoided doing business with Cumberland.

C. LEGISLATION

Concern over the introduction of counterfeit or substandard drugs into the market is nothing new. Over a century ago, Congress first addressed the issue by enacting the original Food and Drugs Act in 1906, which prohibited the trade of "misbranded and adulterated foods, drinks and drugs."[29] Today, the Prescription Drug Marketing Act of 1987 and the Drug Supply Chain Security Act are integral parts of the current federal initiative to secure and protect the pharmaceutical supply chain from substandard drugs entering the market through illegitimate means like counterfeiting and diversion.

[29] FOOD AND DRUG ADMIN., MILESTONES IN U.S. FOOD AND DRUG LAW HISTORY, (Feb. 1, 2018), https://www.fda.gov/about-fda/fdas-evolving-regulatory-powers/milestones-us-food-and-drug-law-history.

i. PRESCRIPTION DRUG MARKETING ACT OF 1987

The Prescription Drug Marketing Act of 1987 (PDMA) established drug pedigree requirements for certain wholesale distributors.[30] The PDMA was designed to "(1) to ensure that drug products purchased by consumers are safe and effective, and (2) to avoid the unacceptable risk to American consumers from counterfeit, adulterated, misbranded, subpotent, or expired drugs."[31] The PDMA requires unauthorized distributors to "provide to the purchaser a statement identifying each prior sale, purchase, or trade of such drug."[32] However, as illustrated by drug diversion schemes like Cumberland Distribution, Inc., merely requiring a distributor to provide a buyer with a pedigree containing the transaction history of a drug does not eliminate the risk of counterfeit or diverted drugs entering the market, as pedigree documents are susceptible to forgery and fraud.

Another potential gap in the protection provided by the PDMA is that only unauthorized distributors are required to provide drug pedigrees.[33] The act defines an unauthorized distributor as "a distributor who does not have an ongoing

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[30] 21 C.F.R. § 203.50 (2006).
[31] FOOD AND DRUG ADMIN., PRESCRIPTION DRUG MARKETING ACT OF 1987, (Mar. 29, 2018), https://www.fda.gov/regulatoryinformation/lawsenforcedbyfda/significantamendmentstothefdcact/prescriptiondrugmarketingactof1987/default.htm.
[32] 21 C.F.R. § 203.50 (2006).
[33] *See* 21 C.F.R. § 203.3 (2008).

relationship with a manufacturer to sell or distribute its products"[34] While many counterfeit or diverted drugs enter the market through such unauthorized distributors, authorized distributors have also introduced counterfeit or diverted drugs into to legitimate as evidenced by Canada Drugs' counterfeiting scheme in which they used authorized shell companies with ongoing relationships with US purchasers.[35] Once in the hands of unknowing, authorized distributors, the diverted or counterfeit drugs could be sold to buyers without the security of providing a drug pedigree to the buyer. While the PDMA surely increased the security of the pharmaceutical supply chain, it left work to be done to further reduce the risk of substandard drugs entering the legitimate market.

ii. DRUG SUPPLY CHAIN SECURITY ACT

In 2013, Congress enacted the Drug Supply Chain Security Act (DSCSA) to address these regulatory gaps in the supply chain left by the PDMA and further protect consumers from counterfeit and diverted drugs, among other things.[36] According to the FDA, the DSCSA "outlines steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are

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[34] 21 C.F.R. § 203.3 (2008).
[35] U.S. ATTORNEY'S OFFICE DISTRICT OF MONTANA, CANADIAN DRUG FIRM ADMITS SELLING COUNTERFEIT AND MISBRANDED PRESCRIPTION DRUGS THROUGHOUT THE UNITED STATES, (Apr. 13, 2018), https://www.justice.gov/usao-mt/pr/canadian-drug-firm-admits-selling-counterfeit-and-misbranded-prescription-drugs.
[36] FDA, DRUG SUPPLY CHAIN SECURITY ACT (DSCSA), (May 22, 2019), https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa.

distributed in the United States."[37] On January 1, 2015, the PDMA's pedigree requirement was replaced by the tracking and tracing standards required by the DSCSA.[38] Additionally, the DSCSA prohibits manufacturers from trading with any unauthorized trading partners, thus at least partially patching the gap left by the PDMA pedigree requirements that only required purchasers to get drug pedigrees from unauthorized distributors before doing business with them.[39]

As for the information that must be supplied under the DSCSA, the act requires the "exchange of transaction information, transaction history, and transaction statements" for each transaction of a drug throughout the supply chain.[40] Transaction information under the DSCSA includes information concerning the name or names of the product, the dosage, the National Drug Code number of the product, the date of the transaction, the lot number, and the names of the businesses involved in the transaction among other things.[41] The DSCSA defines transaction history as, "a statement in paper or electronic form, including the transaction information for each prior transaction going back to the

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[37] *Id.*
[38] FDA, DRUG SUPPLY CHAIN SECURITY ACT PRODUCT TRACING REQUIREMENTS FREQUENTLY ASKED QUESTIONS, (June 29, 2017), https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-product-tracing-requirements-frequently-asked-questions.
[39] 21 U.S.C.A. § 360eee-1(b)(3) (West, Westlaw through Pub. L. No. 116-21).
[40] *Id.* § 360eee-1(a)(2)(A).
[41] *Id*. § 360eee(26).

manufacturer of the product."[42] The transaction statement must state that:

> the entity transferring ownership in a transaction -- (A) is authorized as required under the Drug Supply Chain Security Act; (B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act; (C) received transaction information and a transaction statement from the prior owner of the product, as required under section 360eee-1 of this title; (D) did not knowingly ship a suspect or illegitimate product; (E) had systems and processes in place to comply with verification requirements under section 360eee-1 of this title; (F) did not knowingly provide false transaction information; and (G) did not knowingly alter the transaction history.[43]

It is essential to understand with whom information must be shared under the DSCSA. The DSCSA requires that participants in the drug supply chain provide transaction information, transaction history, and transaction statements to the subsequent entity that is taking ownership of the drug.[44] For example, a manufacturer is required to provide a subsequent wholesale distributor with the required information.[45] Likewise, the wholesale distributor is prohibited from accepting product from a manufacturer that does not provide the required information along with the product.[46] In addition to providing the required information to the subsequent owner, entities must also have

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[42] *Id*. § 360eee(25).
[43] *Id*. § 360eee(27).
[44] *Id.* § 360eee-1(a)(2)(A)(i).
[45] *Id.* § 360eee-1(b)(1)(A).
[46] *Id.* § 360eee-1(c)(1)(A)(i).

"systems and processes necessary to promptly respond with the transaction information and transaction statement for a product upon a request by the Secretary (or other appropriate Federal or State official) in the event of a recall or for the purposes of investigating a suspect product or an illegitimate product shall be required."[47] Additionally each entity must have:

> The systems and processes necessary to promptly facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer, as applicable, shall be required-- (i) in the event of a request by the Secretary (or other appropriate Federal or State official), on account of a recall or for the purposes of investigating a suspect product or an illegitimate product; or (ii) in the event of a request by an authorized trading partner, in a secure manner that ensures the protection of confidential commercial information and trade secrets, for purposes of investigating a suspect product or assisting the Secretary (or other appropriate Federal or State official) with a request described in clause (i).[48]

Thus, upon receiving a request for the information, each entity must be prepared to provide a complete transaction history and transaction information to the Secretary or any other participant who handled the product in the supply chain, regardless of whether they directly engaged with one another or whether there were other market participants,

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[47] *Id.* § 360eee-1(g)(1)(D).
[48] *Id.* § 360eee-1(g)(1)(E).

further removed, that exchanged the product in between them.[49]

The DSCSA gave companies a ten-year deadline to implement the act's tracking system requirements, mandating that all companies involved in the pharmaceutical supply chain implement a system allowing for the traceability of drugs at individually by November 27, 2023.[50] The DSCSA's provided path to compliance can be broken down into three distinct stages of implementation: product verification, serialization, and traceability.[51] To achieve the first step of product verification, companies must be able to promptly provide the FDA with the product's chain of custody at any time so that the FDA can verify it.[52] To achieve the second stage of serialization, companies must create a system by which they can identify each product at a unit level which can be utilized for identification on lots, cases, and packages.[53] To achieve the final step requiring traceability on the product level, companies must have in place the interoperable system which can store information from each transaction; such a

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[49] *Id.* § 360eee-1(g)(1)(E).
[50] *Id.* § 360eee-1(g).
[51] Edwin Lopez, *The Drug Supply Chain Security Act: A Progress Report*, Supply Chain Dive (Apr. 23, 2018), https://www.supplychaindive.com/news/Drug-Supply-Chain-Security-Act-progress-serialization-spotlight/521862/.
[52] *Id*.
[53] *Id*.

system must be in place for every member of the product's supply chain from manufacturers to the final dispensers.[54]

These requirements apply to each member of the supply chain including manufacturers, re-packagers, wholesale distributors, third party logistics providers, and dispensers like pharmacies or hospitals.[55] The Center for Supply Chain Studies has raised concerns with the DSCSA requirement that any given entity in the supply chain must trace transaction information and history through each entity back to the manufacturer, noting that providing this information "could require tens of thousands of electronic connections between previously 'unconnected' participants. Essentially, each supply chain participant might need to form an electronic connection with each potential company participating in their supply chain. *Currently, no such electronic system exists.*"[56] Blockchain appears to be an ideal solution to this problem, given that information stored on a blockchain can be immediately accessed and audited by any member of the network. Transaction information, history, and statements stored on a blockchain platform that is shared between all participants in the product's

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[54] *Id*.
[55] *Id*.
[56] CENTER FOR SUPPLY CHAIN STUDIES, THE DRUG SUPPLY CHAIN SECURITY ACT AND BLOCKCHAIN – A WHITE PAPER FOR STAKEHOLDERS IN THE PHARMACEUTICAL SUPPLY CHAIN, CENTER FOR SUPPLY CHAIN STUDIES (Jun. 21, 2018), https://static1.squarespace.com/static/563240cae4b056714fc21c26/t/5b3a552c2b6a28f30c0c5d31/1530549553630/C4SCS+White+Paper_+DSCSA+and+Blockchain+Study_FINAL4.pdf (emphasis in original).

supply chain could be immediately accessed and audited by any entity in the blockchain's network.[57]

D. CURRENT TRACKING SOLUTIONS

Meeting the DSCSA implementation stages for a complex interoperable tracking system between all members involved in a product's chain of custody in time for the ten-year timeline has proved challenging for companies responsible to implementing the changes.[58] The FDA has been accommodating with regards to these ongoing challenges by pushing back enforcement deadlines.[59] For example, originally the deadline for all manufacturers to serialize their products was November 27, 2017.[60] However in September 2018, following the passage of the original deadline and after receiving requests from smaller contract manufacturing organizations for a grace period[61], the FDA published guidance stating that it would delay enforcement of its product identifier requirements from November 27, 2017, to November 27, 2018.[62] It is not just a few small companies that are

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[57] *See* Maryanne Murray, *Blockchain Explained*, Reuters (Jun 15, 2018), http://graphics.reuters.com/TECHNOLOGY-BLOCKCHAIN/010070P11GN/index.html.

[58] Lopez, *supra* note 51, at 12.
[59] U.S. DEPT. OF HEALTH AND HUMAN SERVS., FOOD AND DRUG ADMIN., et al., *PRODUCT IDENTIFIER REQUIREMENTS UNDER THE DRUG SUPPLY CHAIN SECURITY ACT – COMPLIANCE POLICY,* (Sep. 2018), https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM565272.pdf.
[60] *Id*.
[61] Brajinder Singh, *DSCSA Enforcement Delay – What it Means for You*, (Jul. 3, 2017), https://clarkstonconsulting.com/insights/dscsa-enforcement-delay/.
[62] FDA, *supra* note 59, at 13.

lagging behind the DSCSA's ideal implementation deadlines.[63] A survey of over 660 companies in the pharmaceutical supply chain revealed that only 25% of companies were actually ready to meet the deadline of November 2017.[64] As the November 2018 deadline has come and gone, it appears that more FDA accommodation may be necessary going forward as companies continue to struggle to keep their implantation on track for the final 2023 traceability goal.[65]

Companies are currently incorporating an array of different technologies to build a system for collecting, tracking, and tracing data and for establishing databases for storing and sharing that data. Companies have used radio-frequency identification (RFID), barcodes, and web-based tracking systems based on tracking codes such as the type utilized by FedEx and UPS tracking to track and collect data concerning the pedigree of drugs through the supply chain.[66] The FDA's published guidance for the industry on complying with the DSCSA allows for the use of "paper or electronic versions of invoices; paper versions of packing slips; Electronic Data Interchange (EDI) standards ... EPCIS (Electronic Product Code Information Services), which defines a data-sharing

[63] Lopez, *supra* note 51 at 12.
[64] *Id*.
[65] Health Distribution Alliance, *Three Takeaways from the FDA Public Meetings on DSCSA*, Mar. 26, 2018, https://www.hda.org/news/hda-blog/2018/07/25/08/29/three-takeaways-from-the-fda-public-meetings-on-dscsa.
[66] Susannah Patton, *Cracks in the Pharmaceutical Supply Chain*, Cambridge Innovation Institute, (Jan. 11, 2006), http://www.bio-itworld.com/newsitems/2006/january/11-18-06-news-supply-chain/.

interface that enables supply-chain partners to capture and communicate data about the movement and status of objects in the supply chain."[67] The FDA's guidance notes that email-based or web-based portals for exchanging information are acceptable.[68]

A relational database is one option that companies are utilizing for tracking a drug's pedigree. Data in a relational database is stored in multiple tables that are interrelated–think Master excel spreadsheet combined with its multiple slave spreadsheets. When using a relational database for DSCSA compliance, each manufacturer manages its own database for tracking a product's information. Relational databases allow for easy manipulation of data which is stored in multiple tables in the database, as "[e]ach table of data can be updated without disrupting the others."[69] Additionally any mistakes in the data must be manually checked against the other tables.[70] While the increase manageability of data may be a benefit in some contexts, this is exactly the kind of flexibility that could allow for fraudulent altering of data to create false drug pedigree information in a database. As there is no system for relational databases that automatically detects such changes in data, such breaches could go

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[67] FOOD AND DRUG ADMIN., DSCSA STANDARDS FOR THE INTEROPERABLE EXCHANGE OF INFORMATION FOR TRACING OF CERTAIN HUMAN, FINISHED, PRESCRIPTION DRUGS: HOW TO EXCHANGE PRODUCT TRACING INFORMATION - GUIDANCE FOR INDUSTRY, (2014).
[68] *Id*.
[69] *What is a Relational Database Management System?*, Sisense (2019), https://www.sisense.com/glossary/relational-database/.
[70] *Id*.

unnoticed for some time. Thus, a relational database does not appear to be a good option for DSCSA compliance because "each database owner is responsible for the accuracy, reliability and security of its own database."[71] In other words, it requires trust between parties, something that should be minimized in order to create the most secure system. Blockchain on the other hand, operates without trust between parties.

Another option is the one-up and one-down method in which transaction information is only shared between entities who directly trade with one another. Like a relational database, this system has the weakness of being dependent on each individual entity for the accuracy and security of the information. Additionally, given the DSCSA requirement that parties must be able to make transaction history, transactions information, and transaction statements available to any other party in the drug's supply chain, the one-up and one-down method is a poor option for sharing such information throughout members of the supply chain that are further removed from the party that must share the information.

A database stored on blockchain would provide protection for the gaps left by current methods of tracking data because once

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[71] Nicholas Basta, *Blockchain: the technology to make DSCSA work after 2023?*, Pharmaceutical Commerce (Jul. 24, 2017), http://pharmaceuticalcommerce.com/information-technology/blockchain-technology-make-dscsa-work-2023/.

entered, data stored on a blockchain is nearly impossible to change and the data is instantly available to any party on the network. Thus, unlike current systems of tracking information, a blockchain database offers heightened security, increased auditability, and can operate in an environment devoid of trust.

III. BLOCKCHAIN & SMART CONTRACTS

A. BLOCKCHAIN

When most people hear the term blockchain they likely think of cryptocurrencies like Bitcoin, the first and probably most well-known use of blockchain. Bitcoin was developed in 2008 when a white paper was published under the name Satoshi Nakamoto describing Bitcoin as a peer to peer network designed to fix the problem of double spending of electronic cash, that is fraudulently using the same electronic cash to pay two different people.[72] Blockchain is the underlying technology that supports platforms such as Bitcoin or the smart-contract enabled Ethereum.[73] Blockchain's potential disruptive effect has been compared to that of the internet,[74] and indeed, just like the internet, blockchain technology has the potential to be applied to a wide-

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[72] SATOSHI NAKAMOTO, BITCOIN.ORG, BITCOIN: A PEER-TO-PEER ELECTRONIC CASH SYSTEM 4 (2008), https://bitcoin.org/bitcoin.pdf.
[73] *What is Ethereum?*, http://ethdocs.org/en/latest/introduction/what-is-ethereum.html.
[74] *Blockchain Regulatory Landscape: Key Reference Materials as of April 25, 2018*, 20180510P NYCBAR .5.

array of uses across many different fields.[75] A survey conducted by Deloitte of over 1,000 executives representing companies from seven countries and a wide array of industries including healthcare, technology, pharmaceutical, automotive, oil and gas, and financial services revealed that supply chain is at the top of the list of use cases that companies are currently working on for blockchain technology: (1) supply chain, (2) the internet of things, (3) digital identity, (4) digital records, (5) digital currency, (6) payments, and (7) voting.[76]

At its core, blockchain is a database for recording transactions; it is list of transactions distributed among many different computers on a network.[77] Blockchain is a time-stamped digital ledger that is shared across a decentralized network of computers, known as nodes.[78] Blockchain securely records a chronological log of transactions, events, or any information the user wishes to store.[79] Blockchain uses cryptography to create an immutable record of transactions so that they are extremely hard to change.[80] Additionally, a copy of the entire record is available at

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[75] *See* DELOITTE, *BREAKING BLOCKCHAIN OPEN – DELOITTE'S 2018 GLOBAL BLOCKCHAIN SURVEY (PDF)*(2018) https://www2.deloitte.com/global/en/pages/energy-and-resources/articles/gx-innovation-blockchain-survey.html.
[76] *Id.*
[77] *See* Murray, *supra* note 57, at 13.
[78] *Id.*
[79] *Id.*
[80] *Id.*

all times to all users of a peer-to-peer blockchain network.[81] As a result of this heightened security, blockchain databases may operate as a trustless network, thus eliminating the need for validation of data by third-party intermediaries or central authorities.[82]

There are several different types of blockchain, two of the most significant being private and public blockchains.[83] Understanding the distinctions between private and public chains is important for analyzing which for type of blockchain database would be best suited for the needs of companies within the pharmaceutical supply chain. The main difference between a public and private blockchain is who has access to participate in the network.[84] For a public blockchain, the network is completely open to the public.[85] Participants wishing to join a private blockchain on the other hand must receive an invitation to join the network, and their joining of the network "must be validated by either the network starter or by a set of rules put in place by the network starter."[86] Because the openness of a public blockchain provides less privacy and security for transactions,[87] businesses

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[81] *Id.*
[82] Id.
[83] Praveen Jayachandran, *The difference between public and private blockchain*, IBM (May 31, 2017), https://www.ibm.com/blogs/blockchain/2017/05/the-difference-between-public-and-private-blockchain/.
[84] *Id.*
[85] *Id.*
[86] *Id.*
[87] *Id.*

seeking to implement blockchain networks for purposes of tracking and tracing drugs through the supply chain in compliance with DSCSA would probably be best served by a private blockchain which would allow the parties to limit participants in the network to those parties who are involved in the product's supply chain.

The process in which data is recorded on a blockchain illuminates the meaning behind the term blockchain: a blockchain database is essentially individual blocks of data connected together to form a chain.[88] The process of storing data first begins when a transaction is recorded.[89] Next, the various computers in the network, called nodes, check the details of the transaction to make sure it is valid.[90] The records that the network accepts as valid are then added to a block.[91] Each block contains its own unique code called a hash, as well as the hash of the previous block, and a copy of the data being stored on the block.[92] That block is then added to the blockchain. The hash codes link all of the blocks together in a specific, chronological order, thus forming a chain.[93]

The fact that each block is connected to the next block ad infinitum forming a chain of data is what provides the database with the immutability that is one of blockchain's defining

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[88] *See* Murray, *supra* note 57, at 13.
[89] *Id.*
[90] *Id.*
[91] *Id.*
[92] *Id.*
[93] *Id.*

characteristics.[94] Because each block is linked together through its hash, if someone attempts to alter one single block of data the next block in the chain would no longer recognize the changed block because its hash would not match that of the previous hash.[95] Thus, to successfully change data, the individual would have to recalculate the next block to match up the hashes that link the two.[96] They would then have to repeat that step for every block, recalculating the hash of every single block on the chain, which would take an enormous amount of time and a huge amount of computing power.[97] So, although it is not technically 100% impossible to change the data stored on the chain, the data stored on a blockchain is very, very difficult to alter.[98]

The immutability of data and the permanence that blockchain allows for can be either a benefit or a hindrance depending on the application of the technology. For example, the immutability of data is exactly what makes blockchain technology perfect for a cryptocurrency application like Bitcoin, because once a transaction is recorded on the chain it cannot be changed or deleted, making double spending of electronic currency nearly impossible.[99] On the other hand, the permanent nature of

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[94] *Id.*
[95] *Id.*
[96] *Id.*
[97] *Id.*
[98] *Id.*
[99] SATOSHI NAKAMOTO, BITCOIN.ORG, BITCOIN: A PEER-TO-PEER ELECTRONIC CASH SYSTEM 4 (2008), https://bitcoin.org/bitcoin.pdf.

blockchain has been cause for concern for some people.[100] There are certainly situations in other fields where immutability would be a problem rather than a solution, situations where it would be desirable to be able to alter or delete data.[101] Blockchain may not be the best solution in these particular instances.[102]

IV. ANALYSIS

A. BLOCKCHAIN

In order to best comply with the DSCSA requirement for an "electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States,"[103] companies need a database that allows them to securely and quickly collect, store, and share data concerning a drug's transaction history. Blockchain appears to be the technology best-suited to meet these requirements due to its immutability and decentralization.

Blockchain's characteristic immutability is ideal for purposes of ensuring that transaction information on drug pedigrees are secure, accurate, and compliant with DSCSA standards. Illegal drug diversion and counterfeit drug schemes like the ones Cumberland and Canada Drugs operated rely heavily on

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[100] Jason Bloomberg, *Eight Reasons To Be Skeptical About Blockchain*, Forbes (May 31, 2017), https://www.forbes.com/sites/jasonbloomberg/2017/05/31/eight-reasons-to-be-skeptical-about-blockchain/#10a56a785eb1.
[101] *Id.*
[102] *Id.*
[103] *Id.*

the creation of false drug pedigrees that the offenders fabricate. With no easy way to verify these false drug pedigrees, pharmacies accept the product and end up unknowingly dispensing substandard drugs to customers.[104] The creation of false drug pedigrees would be extremely difficult if the transaction history of a drug were stored on a blockchain database that was shared between all parties on the drug's supply chain. Upon changing hands from the manufacturer to the distributor, this transaction would be permanently recorded on the drug's pedigree which would be stored on a blockchain database. Each transaction down the line would be similarly recorded. The key here with a blockchain is that each party on the network must verify the entry of data, so those wishing to make a false drug pedigree would be unable to go back and alter a drug's pedigree or create a false drug pedigree from scratch, because the entries would not be validated by other members of the chain.

An additional feature of blockchain which makes it a good solution for DSCSA compliance is the fact that it is a decentralized database. Because blockchain is decentralized and data is constantly validated by each member of the network, a process

[104] *See* U.S. v. Charles Jeffrey Edwards (Counts 1 - 28), Brenda Elise Edwards (Counts 1-27), Jerrod Nichols Smith (Counts 1-16; Count 28)., 2013 WL 12210003 (M.D. Tenn.).

known as consensus,[105] a blockchain database would allow for increased visibility, auditability, transparency, and sharing of transaction information with government officials or non-adjacent trading partners.

Multiple businesses and organizations have launched pilot programs that are currently exploring blockchain's potential to improve the pharmaceutical supply chain and achieve DSCSA compliance. Business and supply chain industry leaders such as IBM[106] and GS1[107] are exploring blockchain technology's potential to revolutionize supply chain management. The Center for Supply Chain Studies[108] and the Healthcare Distribution Alliance (HDA)[109] have taken a more specific approach, focusing on blockchain's potential as a pharmaceutical supply chain solution for DSCSA compliance.

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[105] Praveen Jayachandran, *The difference between public and private blockchain*, IBM (May 31, 2017), https://www.ibm.com/blogs/blockchain/2017/05/the-difference-between-public-and-private-blockchain/.

[106] IBM INSTITUTE FOR BUSINESS VALUE, TRUST IN TRADE – TOWARD STRONGER SUPPLY CHAINS, IBM (2016), https://public.dhe.ibm.com/common/ssi/ecm/gb/en/gbe03771usen/gbe03771usen-00_GBE03771USEN.pdf.

[107] GS1, BRIDGING BLOCKCHAINS – INTEROPERABILITY IS ESSENTIAL TO THE FUTURE OF DATA SHARING, GS1 (2018), https://www.gs1.org/sites/default/files/bridging_blockchains_-_interoperability_is_essential_to_the_future_of_da.pdf.

[108] CENTER FOR SUPPLY CHAIN STUDIES, THE DRUG SUPPLY CHAIN SECURITY ACT AND BLOCKCHAIN – A WHITE PAPER FOR STAKEHOLDERS IN THE PHARMACEUTICAL SUPPLY CHAIN, CENTER FOR SUPPLY CHAIN STUDIES (Jun. 21, 2018), https://static1.squarespace.com/static/563240cae4b056714fc21c26/t/5b3a552c2b6a28f30c0c5d31/1530549553630/C4SCS+White+Paper_+DSCSA+and+Blockchain+Study_FINAL4.pdf.

[109] Justine Freisleben, *VRS Update: Past, Present, Future*, HDA (Dec. 12, 2018), https://www.hda.org/news/hda-blog/2018/12/07/14/44/2018-12-12-vrs-update-past-present-future?rtb=1.

GS1, the organization that revolutionized the business and supply chain world when it introduced the barcode in 1974[110], is currently examining blockchain as a supply chain application.[111] GS1 is an organization that helps businesses across the globe improve business communication through implementing supply chain standards like the scannable barcodes you see on essentially everything you purchase from a store.[112] With over a million major businesses such as Coca-Cola, Wal-Mart, and Google, as members of the organization GS1 is in an extremely influential position, and perhaps the best position, to implement blockchain as the new standard for supply chain.[113] Recently GS1 has taken the position that blockchain "will shape the future and rewrite the rules for personal and corporate finance, medicine, supply chain transparency, identity verification, construction and more."[114]

While maintaining that blockchain technology will play a crucial role in setting new standards for global supply chain, a recent paper published by GS1 addresses several "implementation challenges" that businesses should keep in mind while preparing to

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[110] *About GS1*, https://www.gs1.org/about.
[111] *See* GS1, BRIDGING BLOCKCHAINS – INTEROPERABILITY IS ESSENTIAL TO THE FUTURE OF DATA SHARING, GS1 (2018), https://www.gs1.org/sites/default/files/bridging_blockchains_-_interoperability_is_essential_to_the_future_of_da.pdf.
[112] *What we do*, GS1, https://www.gs1.org/about/what-we-do.
[113] *About GS1*, https://www.gs1.org/about.
[114] *GS1 releases new position paper on the future of blockchain technology*, (Oct. 17, 2018), https://www.gs1.org/articles/2463/gs1-releases-new-position-paper-future-blockchain-technology.

implement blockchain.[115] The paper makes it clear that blockchain will not be an overnight solution to current supply chain issues, and that in order to realize the full benefits of a successful blockchain implementation, businesses will have to a invest a great deal of time, effort, and money.[116] Specifically, GS1 identifies four areas as potential implementation challenges: "(1) Business processes around data, (2) Standards and best practices for data, (3) Interoperability and discovery of data between ecosystems, and (4) Governance, including permissions and participation."[117]

GS1 begins by pointing out that most businesses don't currently have systems in place to capture and share the type of data that will be shared throughout the blockchain network.[118] For example, companies' Warehouse Management Systems that "are not designed to collect and share traceability data" will need to implement processes through which they can collect data and share it with not only direct trading partners but also more removed partners throughout the supply chain network.[119] The second challenge businesses will have to overcome in order to successfully implement blockchain is deciding on a set of best

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[115] GS1, BRIDGING BLOCKCHAINS – INTEROPERABILITY IS ESSENTIAL TO THE FUTURE OF DATA SHARING, GS1 (2018), https://www.gs1.org/sites/default/files/bridging_blockchains_-_interoperability_is_essential_to_the_future_of_da.pdf.
[116] *Id.*
[117] *Id.*
[118] *Id.*
[119] *Id.*

practices for data sharing.[120] GS1 notes that one practice gaining favor among industry experts is the practice of "storing a small amount of reference data on enterprise ledgers, while ensuring that richer data can be stored and accessed through applications that reside "off-chain" in traditional data stores."[121] The third challenge companies will face is achieving complete interoperability between various different blockchain networks.[122] The paper notes that there is an increasing number of different types of blockchain networks and that as the number of blockchain networks continues to grow companies must make sure that these different networks are able to communicate with one another if necessary.[123] The fourth and final hurdle companies will face is the issue of governance; that is, companies must decide on "clear set of rules is needed to define the engagement between participants" in the blockchain platform.[124] These rules should address questions like who can participate in the network, what each participant has the power to do in each network, how privacy concerns will be managed, and what data will be stored.[125]

While this GS1 paper broadly focuses on the global supply chain as a whole, each of these four areas of concern are issues that

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[120] *Id.*
[121] *Id.*
[122] *Id.*
[123] *Id.*
[124] *Id.*
[125] *Id.*

pharmaceutical companies will have to grapple with in order to implement blockchain in the pharmaceutical supply chain. While programs such as GS1's point to the conclusion that blockchain is bound to become an integral part of our supply chain at some point in the future, pharmaceutical companies currently face the question of whether they will be able to overcome these obstacles to implementation and have a blockchain system for tracking and tracing drugs in place in time for the various DSCSA deadlines, particularly the final 2023 deadline.

The HDA, a national organization representing primary pharmaceutical distributors, is working on several pilot programs involving blockchain technology to meet the DSCSA tracking and tracing requirements.[126] HDA's Verification Router Service (VRS) which HDA defines as an "interoperable network of companies and technologies that enables verification requests and responses through a look-up directory that is either on a blockchain or where a copy is managed by each solution provider."[127] Testing of the system within both a blockchain and a peer-to-peer network is currently underway, and "testing within the blockchain environment is being managed separately by a blockchain solution

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[126] Justine Freisleben, *VRS Update: Past, Present, Future*, HDA (Dec. 12, 2018), https://www.hda.org/news/hda-blog/2018/12/07/14/44/2018-12-12-vrs-update-past-present-future?rtb=1.
[127] *Id.*

provider."[128] The HDA has forwarded their VRS standards to GS1 and predicts that the program will be completed by January 2019.[129] While the HDA's VRS blockchain is just one example of an application in the pharmaceutical supply chain, its apparent success bodes well for the future of blockchain in the pharmaceutical supply chain.

B. FOOD INDUSTRY AS MODEL FOR IMPLEMENTATION OF BLOCKCHAIN FOR SUPPLY CHAIN

Recent implementations of blockchain to secure the supply chain in the food industry may serve as a useful model for the pharmaceutical industry. In 2017, Walmart, Unilever, Nestle, and other major food companies partnered with IBM to implement a blockchain platform designed to, "maintain secure digital records and improve the traceability of their foodstuffs, like chicken, chocolate, and bananas."[130] For the food industry, tracking food through the use of blockchain technology can be used to improve safety and reduce food borne illness.[131] Currently, investigations into the origin of food borne illnesses take weeks, however

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[128] *Id.*

[129] Justine Freisleben, *Verification Router Service Progress Update*, HDA (Jun. 6, 2018), https://www.hda.org/news/hda-blog/2018/07/25/08/42/verification-router-service-progress-update

[130] Robert Hackett*, Walmart and 9 Food Giants Team Up on IBM Blockchain Plans*, Fortune (Aug. 22, 2017), http://fortune.com/2017/08/22/walmart-blockchain-ibm-food-nestle-unilever-tyson-dole/.

[131] *See* Id.

blockchain could shorten that investigation time to seconds.[132] So far Walmart has experimented with using blockchain to track the import of Chinese pork and Mexican mangoes, and these experiments have been so promising that other companies in the food industry are following Walmart's lead.[133] The Vice President of Food Safety at Walmart stated that, "we believe the one-step-up and one-step-back model of food traceability is outdated for the 21st century.... Leveraging blockchain as the enabling technology and GS1 standards as the universal language, we believe we can create a more digital and transparent food system that will benefit people and the planet."[134]

Howard Popoola, Kroger's VP of corporate food technology and regulatory compliance, has credited Walmart's foray into blockchain with bringing "legitimacy" to blockchain's use in the food industry, noting that, "[t]he food industry is ripe for a solution like that."[135] Poor fruit puns aside, with five years until the DSCSA's 2023 deadline for full compliance, it looks like the pharmaceutical industry is ripe for its own blockchain solution. Just as food companies are beginning to use blockchain to track

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[132] *Id.*
[133] *Id.*
[134] GS1, BRIDGING BLOCKCHAINS – INTEROPERABILITY IS ESSENTIAL TO THE FUTURE OF DATA SHARING, GS1 (2018), https://www.gs1.org/sites/default/files/bridging_blockchains_-_interoperability_is_essential_to_the_future_of_da.pdf.
[135] Robert Hackett*, Walmart and 9 Food Giants Team Up on IBM Blockchain Plans*, Fortune (Aug. 22, 2017), http://fortune.com/2017/08/22/walmart-blockchain-ibm-food-nestle-unilever-tyson-dole/.

food products "across a complex network that includes farmers, brokers, distributors, processors, retailers, regulators, and consumers,"[136] pharmaceutical companies should follow suit by using blockchain to track pharmaceuticals across the complex network of manufacturers, wholesale distributors, and dispensers. The pharmaceutical industry and the food industry face similar issues concerning protecting their supply chains against contaminated products. In both industries, tracking and tracing of products is essential to protecting the end consumer from dangers like contaminated drugs or food.

V. CONCLUSION

As blockchain continues to gain momentum and gain legitimacy as a technology with various business applications it seems likely that it could eventually be a major disruptor in supply chain on a global scale. With industry leaders such as IBM and GS1 putting substantial efforts into helping businesses implement blockchain for supply chain management this goal may be realized sooner rather than later. The characteristics of blockchain, particularly its immutability and decentralized structure, make it appear as if the technology was designed as a solution for tracking requirements of the DSCSA. With a blockchain database in place companies could easily share data across a large network of trading partners and could instantly provide necessary transaction

[136] *Id.*

information to governmental agencies that request it. Additionally, due to the difficulty of altering or deleting data once it is stored on the blockchain, fraudulently created false drug pedigrees that allow counterfeit and diverted drugs to enter the legitimate market may become a thing of the past. While blockchain seems a perfect fit for DSCSA compliance, it remains to be seen whether businesses will be able to implement the technology in time for the 2023 deadline prescribed by the DSCSA.

With the great potential blockchain is showing, it may be beneficial for the FDA to continue to monitor industry progress and make accommodations necessary with regard to enforcement of DSCSA requirements, including potentially extending its deadline for compliance. Extending the end deadline for compliance would allow the FDA to ensure that businesses in pharmaceutical industry have appropriate time to properly develop and implement the best possible supply chain solution. Implementing blockchain will take time, but it appears to be the best solution to the supply chain problems addressed by the DSCSA. While meeting the 2023 deadline would be ideal, this quickly approaching deadline could lead businesses to hurriedly work on existing systems to make them DSCSA compliant rather than dedicating their time and money to develop blockchain which could provide the best possible solution in the long term.