Int. j. adv. multidisc. res. stud. 2024; 4(6):1730-1739

Received: 11-11-2024
Accepted: 21-12-2024

International Journal of Advanced Multidisciplinary Research and Studies

ISSN: 2583-049X

Combating Counterfeit Drugs in the U.S. Pharmaceutical Supply Chain: The Potential of Blockchain and IoT for Public Health Safety

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DOI: https://doi.org/10.62225/2583049X.2024.4.6.4103
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Abstract

Counterfeit drugs pose a significant public health threat in the U.S., undermining patient safety, causing economic losses, and complicating regulatory efforts. Despite existing measures like the Drug Supply Chain Security Act (DSCSA), the pharmaceutical supply chain remains vulnerable to fraudulent activities due to fragmented data and a lack of real-time tracking. This paper explores the potential of blockchain and Internet of Things (IoT) technologies to strengthen the pharmaceutical supply chain and mitigate the risks posed by counterfeit drugs. Blockchain offers an immutable, decentralized ledger that ensures the traceability and authenticity of pharmaceuticals, while IoT enables real-time monitoring of conditions such as temperature and humidity throughout the distribution process. Together, these technologies create a transparent, secure system that improves supply chain visibility and reduces the likelihood of counterfeit products entering the market. However, implementing these technologies faces challenges, including technical scalability, regulatory alignment, and cost barriers. Policy recommendations and industry collaboration strategies must address these challenges and enable widespread adoption. Future research should optimize blockchain-IoT integration, enhance sensor capabilities, and develop global standards to ensure interoperability. By leveraging blockchain and IoT, the pharmaceutical industry can enhance drug safety, improve compliance, and ensure a more robust supply chain against counterfeiting.

Keywords: Counterfeit Drugs, Pharmaceutical Supply Chain, Blockchain, Internet of Things (IoT), Drug Safety

1. Introduction

1.1 Overview of Counterfeit Drugs as a Public Health Threat in the U.S.

Counterfeit drugs have become a significant threat to public health globally, and the U.S. is no exception. The U.S. pharmaceutical market is a major target for counterfeiters, primarily due to its size, regulatory gaps, and the potential for immense profits (Mackey & Nayyar, 2017) [38]. Counterfeit drugs are those that are deliberately mislabeled with respect to their identity or source, which can include both branded and generic medicines. These counterfeit medicines may contain incorrect ingredients, insufficient active ingredients, or dangerous contaminants that pose serious health risks to patients (Isles, 2017) [28]. According to the World Health Organization (WHO), around 10% of medicines worldwide are estimated to be counterfeit, varying based on region and product category (Organization, 2017b) [46]. In the U.S., while regulatory efforts are stronger compared to other regions, counterfeit drugs still enter the supply chain due to weaknesses in the system. The rise in online pharmacies and the growing demand for drugs in developing regions exacerbate this issue, providing opportunities for counterfeit drugs to be sold without detection (Al-Worafi, 2020a) [11].

Counterfeit drugs not only endanger patient safety but also undermine the efficacy of treatments, contribute to antibiotic resistance, and may lead to adverse drug reactions, hospitalizations, and even fatalities. In certain cases, counterfeit drugs are indistinguishable from legitimate medications, making them difficult to detect without thorough investigation. This increasing threat to public health and safety has prompted calls for enhanced security measures in the pharmaceutical supply chain (Al-Worafi, 2020b) [12].

The consequences of counterfeit drugs are profound. On a patient safety level, these drugs fail to provide the necessary therapeutic effect, which can result in prolonged illness, worsened medical conditions, or even death. In some cases, counterfeit drugs may contain toxic substances or harmful levels of unregulated chemicals that exacerbate health problems. Additionally, counterfeit medications often target high-demand drugs, such as those used in treating chronic diseases or life-threatening conditions like cancer or cardiovascular diseases, further magnifying the risks (Kutner *et al*., 2015) [37].

Beyond patient safety, counterfeit drugs have a substantial economic impact on the healthcare system. They result in higher treatment costs, extended hospital stays, and increased burden on healthcare providers, who must identify and manage the consequences of these counterfeit products. Furthermore, the presence of counterfeit drugs in the market can damage the reputations of legitimate pharmaceutical companies and undermine consumer confidence in the safety of medications. The financial losses from counterfeit drugs are significant, with estimates ranging in the billions annually in the U.S. alone (Organization, 2019) [47].

From a regulatory standpoint, the fight against counterfeit drugs presents numerous challenges. Regulatory bodies such as the Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA) have developed frameworks and policies to address counterfeiting, but these systems have limitations (Halabi, 2015) [25]. Traditional methods of tracking and verifying drug authenticity, such as serial numbers and batch codes, have proven to be insufficient in preventing the infiltration of counterfeit drugs into the market. The increasing sophistication of counterfeiters and their ability to bypass current systems has led to calls for more robust and dynamic solutions (Kumar & Baldi, 2016) [36].

1.2 Existing Regulatory Frameworks and Their Limitations in Addressing Counterfeiting

In response to the growing issue of counterfeit drugs, regulatory frameworks such as the Drug Supply Chain Security Act (DSCSA) were introduced. The DSCSA, enacted as part of the Drug Quality and Security Act in 2013, aims to establish a secure and traceable drug distribution system. Its primary goals are to track and trace prescription drugs as they move through the supply chain and verify pharmaceutical products' legitimacy (Brechtelsbauer, Pennell, Durham, Hertig, & Weber, 2016) [16].

While the DSCSA has made strides in improving drug supply chain security, it faces several limitations. First, the act only mandates tracking for certain categories of drugs, leaving gaps for other drug types that may be vulnerable to counterfeiting. Moreover, the DSCSA's reliance on paper-based systems, serial numbers, and barcodes does not provide real-time, tamper-proof tracking, leaving room for fraudulent activities. The lack of interoperability among various tracking systems and stakeholders further complicates the enforcement of regulations. Consequently, counterfeiters can exploit these loopholes to introduce falsified drugs into the market.

Additionally, the DSCSA's effectiveness is hindered by inconsistent enforcement and a lack of standardized protocols across the supply chain. For instance, not all manufacturers, distributors, or pharmacies must comply with the same stringent standards, and there are varying levels of vigilance when verifying drug authenticity (Uddin, Salah, Jayaraman, Pesic, & Ellahham, 2021) [53].

1.3 Blockchain and IoT as Potential Solutions

Blockchain and the Internet of Things (IoT) present promising technologies that could revolutionize how counterfeit drugs are addressed within the U.S. pharmaceutical supply chain. Blockchain technology, with its decentralized and immutable ledger system, provides a secure way to track the movement of pharmaceuticals at every stage of the supply chain. Each transaction on the blockchain is recorded transparently, and tamper-proof, ensuring that any attempt to introduce counterfeit drugs into the supply chain can be easily detected (Singh, Dwivedi, & Srivastava, 2020) [52].

When integrated with IoT devices, blockchain can provide real-time data on the condition and location of drugs throughout their journey. IoT sensors such as RFID tags, GPS trackers, and environmental monitoring devices can be used to ensure the drugs are stored and transported under the correct conditions (Nanda, Panda, & Dash, 2023) [41]. These sensors can transmit data to the blockchain, where it is securely stored, and stakeholders in the supply chain can monitor the movement of drugs, validate their authenticity, and detect potential risks. Blockchain and IoT can create a more transparent, efficient, and secure pharmaceutical supply chain. These technologies can significantly reduce the risk of counterfeit drugs entering the market by enabling real-time tracking, tamper-proof documentation, and automated alerts for discrepancies (Agarwal *et al*., 2022) [9].

1.4 Research Aim

This paper aims to explore the integration of blockchain and IoT technologies into the U.S. pharmaceutical supply chain as a solution to combat the growing threat of counterfeit drugs. Specifically, this paper will examine the capabilities of blockchain and IoT in improving drug traceability, enhancing regulatory compliance, and ensuring the integrity of pharmaceutical products. The research will highlight how combining these technologies can address the limitations of existing regulatory frameworks, provide a higher level of security, and improve public health outcomes.

The study will also evaluate the potential challenges and barriers to implementing blockchain and IoT in the pharmaceutical supply chain, including technological hurdles, regulatory considerations, and cost factors. Through this examination, the paper proposes actionable recommendations for stakeholders within the pharmaceutical industry and policymakers to leverage these technologies effectively.

2. Counterfeit Drugs and Challenges in the Pharmaceutical Supply Chain

2.1 The Scale and Economic Burden of Counterfeit Pharmaceuticals

The proliferation of counterfeit drugs is a global crisis that disproportionately impacts the pharmaceutical industry, posing severe consequences for public health, economic stability, and the efficacy of health interventions. In the U.S., counterfeit drugs represent a growing challenge, with counterfeiters exploiting gaps in regulatory frameworks and technological vulnerabilities within the supply chain. The scale of the issue is staggering, and the economic burden on

the healthcare system and pharmaceutical industry is significant (A. Adekola & S. Dada, 2024; M. Adelodun & E. Anyanwu, 2024) [1, 5].

The World Health Organization estimates that up to 10% of medicines worldwide are counterfeit, with certain regions and therapeutic classes (such as oncology or cardiovascular medications) experiencing higher rates of fakes entering the market. In the U.S., the number may be lower but it is still concerning, particularly in online pharmacies and cross-border shipments where enforcement of anti-counterfeiting laws is difficult. The global pharmaceutical market is worth trillions of dollars, and counterfeit drugs represent a small but damaging fraction of this market. Counterfeit medications can take many forms, ranging from drugs with incorrect or substandard ingredients to medicines that are entirely fake (Organization, 2017a) [45].

The economic impact of counterfeit drugs is multi-faceted. Counterfeit medicines are estimated to cost the global pharmaceutical industry billions annually in lost revenue, with some estimates suggesting losses of over $200 billion per year. For pharmaceutical companies, introducing counterfeit drugs into the market can result in a significant drop in sales as consumer trust is eroded. The costs associated with recalling counterfeit drugs, conducting investigations, and addressing legal claims are immense (A. D. Adekola & S. A. Dada, 2024b) [3]. In addition to the direct financial impact on the industry, counterfeit drugs increase healthcare costs by requiring additional treatments to address adverse effects, complications from incorrect dosing, or the failure of counterfeit drugs to provide the necessary therapeutic benefits.

Beyond direct financial losses, counterfeit drugs also undermine the efficacy of public health efforts. For example, counterfeit antiretroviral drugs in the treatment of HIV/AIDS can contribute to drug resistance, making treatment regimens less effective and complicating future treatment strategies. Similarly, counterfeit antibiotics may fail to adequately treat infections, contributing to the growing global crisis of antimicrobial resistance (AMR). The consequences of these failures are not limited to individual patients but extend to broader public health systems, leading to longer hospital stays, increased mortality, and an overall higher burden on healthcare resources (M. O. Adelodun & E. C. Anyanwu, 2024a) [6].

2.2 Weaknesses in the Current Pharmaceutical Supply Chain

Although robust in some aspects, the pharmaceutical supply chain has several vulnerabilities that make it susceptible to counterfeit infiltration. One of the most significant weaknesses is the lack of real-time tracking and traceability of drug products as they move through the supply chain. While drugs are tracked to some extent through barcodes, serial numbers, and shipping labels, these systems are not foolproof. Counterfeiters can easily replicate or modify these identifiers, allowing fake drugs undetected to enter the legitimate supply chain. As a result, the effectiveness of tracking systems is limited, and the ability to quickly identify and recall counterfeit products is hindered (M. O. Adelodun & E. C. Anyanwu, 2024b; Adewumi, Dada, Azai, & Oware, 2024) [7, 8].

The fragmentation of the pharmaceutical supply chain further complicates the challenge of ensuring drug authenticity. Before reaching patients, drugs typically pass through multiple intermediaries, including manufacturers, wholesalers, distributors, and pharmacies. At each step, there is the potential for errors, deliberate tampering, or the introduction of counterfeit drugs. Each entity operates on different systems and protocols, which may not be integrated or standardized. The lack of interoperability between these systems makes it difficult to track drugs in real-time across the entire supply chain, increasing the likelihood that counterfeit drugs can be distributed and sold to consumers.

Another critical weakness in the pharmaceutical supply chain is the lack of effective and comprehensive data-sharing mechanisms between stakeholders. Information about the movement and condition of drugs is often siloed within individual companies or segments of the supply chain. This lack of data transparency means that if a counterfeit drug enters the supply chain, it can be difficult for other entities to detect or respond promptly. This fragmented data landscape exacerbates the problem of identifying fake drugs before they reach consumers (Akram *et al*., 2024) [10].

The reliance on manual record-keeping and paper-based systems in some supply chains also contributes to inefficiency and potential vulnerabilities. Without secure, real-time digital tracking and verification methods, counterfeit drugs can easily bypass traditional inspection procedures. The result is that counterfeiters can introduce fake medicines at various stages of the supply chain with little risk of detection until it is too late (A. D. Adekola & S. A. Dada, 2024a, 2024c) [2, 4].

2.3 Regulatory Efforts and Enforcement Challenges in Detecting and Preventing Counterfeit Drugs

Regulatory bodies such as the U.S. Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA) have implemented various measures to combat the issue of counterfeit drugs. One of the key regulatory tools is the Drug Supply Chain Security Act (DSCSA), which mandates that pharmaceutical products be tracked and traced through the supply chain. DSCSA aims to establish an electronic, interoperable system that ensures the authenticity of drugs and allows for the quick identification and removal of counterfeit drugs from the market. However, the DSCSA has proven insufficient in fully addressing the scale of the problem.

Despite the efforts of the FDA and other regulatory agencies, enforcement remains a major challenge. Counterfeiters have become increasingly sophisticated in their methods, using high-tech equipment to replicate packaging and labeling with remarkable precision. Even when counterfeit drugs are identified, the logistics of recalling them from the supply chain can be cumbersome and slow. Since the supply chain is fragmented and different parts of the process involve different actors, recall coordination often involves many stakeholders and can take days or weeks. Counterfeit drugs may continue circulating at that time, putting patients at risk (Alli & Dada, 2024; Banji, Adekola, & Dada, 2024a) [13, 14].

Another key challenge in enforcing anti-counterfeiting measures is the complexity of international trade. Many counterfeit drugs enter the U.S. from overseas, often through illicit online pharmacies or gray-market distributors. These international supply chains are difficult to monitor and regulate, making it challenging for U.S. authorities to ensure

the authenticity of every imported drug. The prevalence of online pharmacies further complicates enforcement, as consumers may unknowingly purchase counterfeit drugs from unregulated sources.

The lack of a universal, standardized approach to drug authentication across different markets and regulatory frameworks adds another layer of difficulty. The U.S. regulatory system may not align with those in other countries, leading to discrepancies in the tracking and verification of drug products. Counterfeit drugs can more easily slip through the cracks without uniform global standards (Banji, Adekola, & Dada, 2024b; Drakeford & Majebi, 2024a) [15, 17].

2.4 The Role of Intermediaries and Vulnerabilities in Traditional Drug Distribution Channels

The pharmaceutical distribution system involves numerous intermediaries, each of whom plays a role in the movement of drugs from manufacturers to end-users. These intermediaries include wholesalers, distributors, brokers, and pharmacies, all of whom are essential for the efficient functioning of the supply chain. However, the involvement of multiple parties increases the system's complexity and introduces vulnerabilities that counterfeiters can exploit.

One of the key vulnerabilities in the traditional drug distribution channel is the lack of direct oversight and accountability. As drugs pass through numerous hands before reaching consumers, each intermediary may have limited visibility into the previous stages of the drug's journey. While manufacturers are responsible for the initial production and packaging of drugs, the involvement of wholesalers and distributors can sometimes muddy the waters, with counterfeit drugs slipping through unnoticed (Hall & Antonopoulos, 2016) [26].

Additionally, the varying levels of regulatory compliance and enforcement across different intermediaries can create opportunities for counterfeit drugs to enter the supply chain. Some intermediaries may be more diligent about following regulatory guidelines, while others may be more lax, either due to oversight or deliberate negligence. This inconsistency makes it difficult to establish a unified, transparent approach to combating counterfeit drugs.

The rise of gray-market distributors, who often operate in unregulated or under-regulated environments, further exacerbates the supply chain's vulnerability. These distributors often engage in the purchase of drugs from sources that are not officially authorized, such as international markets or unlicensed sellers. The sale of counterfeit drugs through these channels can bypass normal regulatory checks and contribute to the spread of fake medicines (Drakeford & Majebi, 2024c, 2024e) [19, 21].

In conclusion, the pharmaceutical supply chain is plagued by various vulnerabilities that enable counterfeit drugs to enter and circulate undetected. Weaknesses such as lack of real-time tracking, fragmented data, insufficient regulatory enforcement, and the role of intermediaries all contribute to the persistence of this global problem. To address these challenges, adopting more sophisticated and integrated technological solutions that enhance transparency, traceability, and accountability throughout the supply chain is crucial.

3. The Role of Blockchain and IoT in Strengthening Pharmaceutical Supply Chains

3.1 Blockchain for Transparency and Traceability

Blockchain technology has emerged as a revolutionary solution for enhancing transparency and traceability within the pharmaceutical supply chain. The decentralized and immutable nature of blockchain makes it uniquely suited for tracking the movement of drugs from manufacturers to end-users. By providing an unalterable record of each transaction and interaction, blockchain ensures that every step in the supply chain is securely documented. This visibility mitigates the risks of counterfeiting by making it nearly impossible for counterfeit drugs to infiltrate the legitimate supply chain without detection.

In a blockchain-powered pharmaceutical supply chain, each drug product is assigned a unique identifier, which is recorded on the blockchain as it moves through different supply chain stages. This identifier, linked to a specific batch or serial number, provides an audit trail accessible by all authorized parties, from manufacturers to wholesalers to end consumers. Once a transaction is entered into the blockchain, it becomes a permanent record that cannot be altered without the network's consensus, thus ensuring data integrity and preventing fraud. This makes blockchain particularly valuable for ensuring the authenticity of drugs as they pass through various touchpoints in the supply chain (Ogwel, 2020) [44].

Blockchain also addresses the issue of data fragmentation in the pharmaceutical supply chain. In traditional systems, different stakeholders in the supply chain may maintain their own records, creating silos of information that are not easily shared or integrated (Agarwal *et al*., 2022) [9]. Blockchain removes these silos by providing a shared, transparent ledger where all stakeholders can access real-time information about drug movements. This facilitates easier coordination between manufacturers, distributors, and retailers, and allows for faster identification of counterfeit drugs if they enter the system. The immutability of blockchain ensures that once data is recorded, it cannot be tampered with, providing an additional layer of security to prevent fraud (Katuwal, Pandey, Hennessey, & Lamichhane, 2018) [29].

Smart contracts, another feature of blockchain, further enhance compliance and enforcement. Smart contracts are self-executing contracts with the terms of the agreement directly written into code. In the context of pharmaceuticals, these contracts can be programmed to enforce regulatory compliance automatically, such as confirming that drugs have been transported under the required conditions or that proper documentation has been provided at each stage of the supply chain. This can include verifying the temperature of drugs during transit, ensuring proper storage conditions, and automatically verifying authenticity based on the blockchain records. Smart contracts help to reduce human error, speed up verification processes, and increase efficiency in compliance monitoring (Drakeford & Majebi, 2024d; Edoh, Chigboh, Zouo, & Olamijuwon, 2024) [20, 22].

Several pilot projects and case studies have demonstrated the efficacy of blockchain in pharmaceutical tracking. For instance, the MediLedger project, a collaboration between major pharmaceutical companies, aims to create a

blockchain-based system for verifying the legitimacy of drug products and preventing the entry of counterfeit medicines into the U.S. market (Akram *et al*., 2024) [10]. Similarly, the use of blockchain has been tested by companies such as IBM and Walmart in tracking the supply chain of food and pharmaceuticals, ensuring that products are genuine and have not been tampered with. These case studies illustrate how blockchain can provide a robust solution for ensuring the integrity of pharmaceutical supply chains and protecting public health.

3.2 IoT for Real-Time Monitoring and Authentication

The integration of the Internet of Things (IoT) into pharmaceutical supply chains significantly enhances the ability to monitor drugs in real time, addressing issues such as temperature excursions and product authenticity. IoT involves the use of connected devices, sensors, and RFID tags to collect and transmit data about the conditions and movement of products. These devices can be placed on drug containers, packaging, or storage units to track various parameters such as location, temperature, humidity, and even light exposure, which can be critical for maintaining the efficacy of sensitive pharmaceutical products (Hernández & Yamaura, 2017) [27].

Radio Frequency Identification (RFID) tags and Near Field Communication (NFC) are among the most common IoT technologies used in the pharmaceutical supply chain. RFID tags allow for the identification and tracking of drugs as they move through the supply chain, providing real-time visibility into their location. These tags can store a range of information about the drug, including batch numbers, expiration dates, and shipment history, which authorized stakeholders can access at any point in the supply chain. NFC, a short-range communication technology, can also be used for contactless data transmission between devices, ensuring efficient tracking without the need for physical scans or direct interaction (El Matbouly, Nikbakhtnasrabadi, & Dahiya, 2022) [23].

One of the key applications of IoT in pharmaceutical supply chains is real-time monitoring of environmental conditions, particularly for temperature-sensitive drugs. Many pharmaceuticals, such as vaccines or biologics, require strict temperature control during storage and transport to remain effective. IoT-enabled sensors can continuously monitor the temperature of these drugs and alert stakeholders if there is any deviation from the required range. For example, suppose a shipment of vaccines experiences a temperature excursion. In that case, IoT sensors can notify the logistics team immediately, enabling quick corrective actions such as rerouting the shipment or replacing the compromised product. This real-time data collection helps prevent the distribution of degraded or ineffective drugs, protecting both patient safety and public health (Drakeford & Majebi, 2024b; M. Kelvin-Agwu, M. O. Adelodun, G. T. Igwama, & E. C. Anyanwu, 2024b) [18, 31].

Furthermore, IoT sensors can be used to authenticate products by verifying their condition and status during each stage of the supply chain. Smart packaging, equipped with IoT sensors, can detect tampering or unauthorized access to the product, providing an additional layer of security against counterfeiting. These sensors can detect if a package has been opened, altered, or exposed to conditions that could compromise the integrity of the drug. This ensures that only drugs that meet the required standards reach the consumer and that any counterfeit or compromised drugs are quickly identified and removed from the supply chain (Pal & Kant, 2020) [49].

By providing continuous, real-time data about the conditions and movement of drugs, IoT technologies offer a more efficient and effective method of tracking pharmaceuticals than traditional systems. Real-time monitoring ensures that any irregularities can be detected immediately, reducing the chances of counterfeit drugs entering the market. IoT also enables faster response times in case of a problem, such as a temperature breach or a shipment delay, ensuring that corrective actions are taken before the drugs reach patients.

3.3 Synergies Between Blockchain and IoT for End-to-End Visibility

When combined, blockchain and IoT offer a powerful, synergistic solution to the challenges of counterfeit drugs and supply chain inefficiencies in the pharmaceutical industry. While IoT provides the real-time data collection and monitoring capabilities necessary to ensure the integrity of drugs as they move through the supply chain, blockchain provides the decentralized, immutable ledger that ensures transparency, security, and traceability. Together, these technologies create an end-to-end visibility system that tracks drugs at each stage and guarantees their authenticity and condition.

For example, IoT-enabled sensors can collect data about the environmental conditions of a drug shipment, such as temperature, humidity, and exposure to light. This data can then be recorded on the blockchain, ensuring an immutable, transparent record of the drug's condition throughout its journey (Poongodi, Agnesbeena, Janarthanan, & Balusamy, 2020) [50]. Suppose any deviation from the required conditions, such as a temperature breach. In that case, the data can trigger a smart contract on the blockchain to notify stakeholders and take automated corrective actions, such as rerouting the shipment or alerting the manufacturer. This integration of real-time monitoring and secure, transparent data storage ensures that all parties in the supply chain are informed about the status of the drugs, reducing the risk of counterfeit products or compromised shipments (M. Kelvin-Agwu, M. O. Adelodun, G. T. Igwama, & E. C. Anyanwu, 2024a; M. C. Kelvin-Agwu, M. O. Adelodun, G. T. Igwama, & E. C. Anyanwu, 2024a) [30, 32].

Moreover, the combination of blockchain and IoT enables seamless collaboration between stakeholders in the pharmaceutical supply chain. Manufacturers, wholesalers, distributors, and retailers can all access the same real-time data, ensuring they have up-to-date information about the drugs they are handling. This shared visibility promotes greater accountability and trust among supply chain participants, helping to prevent the entry of counterfeit drugs and ensuring that all parties comply with regulatory requirements (Oriekhoe, Ashiwaju, Ihemereze, Ikwue, & Udeh, 2024) [48].

4. Challenges and Considerations for Implementation

4.1 Technical Barriers

While promising, the adoption of blockchain and IoT technologies in the pharmaceutical supply chain faces several technical barriers that must be addressed for successful implementation. One of the primary challenges is scalability. Blockchain, by design, involves recording every transaction on a decentralized ledger. As the pharmaceutical

supply chain is vast, with a large volume of transactions occurring across various stakeholders, the sheer scale of data generated may create bottlenecks in blockchain systems (Nguyen *et al*., 2019) [42]. Traditional blockchain models, such as those used in cryptocurrency networks, can struggle with processing many transactions per second, leading to delays in recording real-time data. To address this challenge, scalable blockchain solutions that can handle high throughput and rapid transaction speeds are necessary. These include adopting newer consensus algorithms like Proof of Authority or Delegated Proof of Stake, which are more efficient than traditional Proof of Work (Ferdous, Chowdhury, Hoque, & Colman, 2020) [24].

In addition to scalability, data storage constraints pose another hurdle. Blockchain technology requires significant storage capacity, especially when storing large amounts of transactional data from the supply chain. All information, from manufacturing details to transportation logs, is recorded on the blockchain, contributing to its overall size. However, storing every transaction on-chain can lead to bloated systems and higher costs, particularly in a supply chain as large and complex as that of the pharmaceutical industry. Solutions like off-chain storage or distributed file systems, such as IPFS (InterPlanetary File System), can mitigate these challenges by storing large files outside the blockchain while maintaining links to the main ledger, ensuring scalability without compromising data integrity (M. C. Kelvin-Agwu, M. O. Adelodun, G. T. Igwama, & E. C. Anyanwu, 2024c; Majebi, Adelodun, & Anyanwu, 2024a) [34, 39].

Another critical technical challenge is integrating blockchain and IoT with legacy systems currently used by stakeholders in the pharmaceutical supply chain. Many pharmaceutical companies and distributors have well-established infrastructures that may not be compatible with blockchain and IoT technologies. These legacy systems often operate in silos, relying on outdated technologies that may not support the real-time data sharing and decentralized model inherent to the blockchain. To achieve successful integration, companies must invest in technology upgrades, implement new interfaces, or adopt hybrid solutions that bridge the gap between new blockchain systems and legacy software. This requires both technical expertise and considerable financial investment, making it a barrier for companies that lack the resources for such transformations.

4.2 Regulatory and Compliance Issues

Stringent regulations govern pharmaceutical supply chains to ensure drug safety, efficacy, and security. The U.S. Food and Drug Administration (FDA) and the Drug Supply Chain Security Act (DSCSA) are two key regulatory frameworks that govern drug tracking and verification in the country. The introduction of blockchain and IoT technologies must align with these regulations to ensure compliance and prevent any legal conflicts.

One of the primary challenges in implementing blockchain and IoT solutions is ensuring that the technologies meet FDA regulations, particularly around drug traceability and safety requirements. The FDA's pharmaceutical supply chain management guidelines mandate that manufacturers, wholesalers, and distributors must track and trace drugs to prevent the distribution of counterfeit medications. Blockchain's role in providing immutable, transparent records can support this requirement. However, blockchain systems must be tailored to ensure they can record data aligning with FDA protocols, including specific timestamps, digital signatures, and secure data formats. Additionally, blockchain's ability to enable real-time reporting of adverse events or drug recalls would significantly enhance public health safety, ensuring swift action in case of any drug issues (M. C. Kelvin-Agwu, M. O. Adelodun, G. T. Igwama, & E. C. Anyanwu, 2024b; Majebi, Adelodun, & Anyanwu, 2024b) [33, 40].

Furthermore, compliance with the DSCSA is a significant consideration. This legislation requires pharmaceutical companies to maintain detailed records of the movement of prescription drugs through the supply chain. Blockchain can support this requirement by providing an indelible audit trail, ensuring that each drug's movement can be verified against the DSCSA standards. However, integrating blockchain technology must align with the DSCSA's specific tracking and reporting procedures. This may require legal and regulatory adjustments to accommodate the new technology and collaboration with regulatory bodies to ensure that the blockchain solutions comply with current and future regulations.

Aligning IoT technologies with FDA and DSCSA requirements also involves addressing privacy and data protection concerns. IoT sensors and devices generate large amounts of data, and ensuring the security and privacy of this data is paramount. IoT systems must be designed to adhere to regulatory standards, such as ensuring that personal health information is properly protected during data transmission and storage (Akram *et al*., 2024) [10].

4.3 Cost and Adoption Challenges

Implementing blockchain and IoT solutions in pharmaceutical supply chains has financial challenges. One of the most significant barriers to adoption is the upfront investment required for these technologies. Blockchain development, IoT sensors, and integrating these systems into existing infrastructure all come with substantial costs. For small to medium-sized enterprises (SMEs) in the pharmaceutical industry, the high cost of implementation can be a major deterrent. The cost of developing, deploying, and maintaining blockchain systems, along with purchasing IoT devices and sensors, can exceed the budgets of many stakeholders, particularly in the early stages.

Furthermore, the need for industry-wide standardization complicates the financial and operational landscape. Blockchain and IoT systems must be interoperable across the entire supply chain, from manufacturers to wholesalers to retailers. However, the pharmaceutical industry currently lacks unified standards for data formats, protocols, and compliance requirements. Without a common framework, companies may be hesitant to invest in solutions that are not guaranteed to work across the entire supply chain. Establishing industry-wide standards for blockchain and IoT solutions would provide clarity for companies looking to invest in these technologies and encourage broader adoption.

In addition to the financial burden, resistance from stakeholders is another challenge. Many pharmaceutical companies, distributors, and other supply chain participants are accustomed to traditional methods and may resist adopting new technologies. The perceived complexity of blockchain and IoT, along with concerns about the learning curve and the potential disruption to established business

practices, can create hesitation among stakeholders. Overcoming this resistance requires financial incentives education and training to demonstrate the long-term benefits of these technologies, including enhanced security, reduced counterfeiting, and improved operational efficiency (Ogbonna, Oparaocha, Anyanwu, & Innocent, 2024) [43].

4.4 Cybersecurity Risks: Potential Threats and Strategies to Ensure Secure Implementation

As with any digital solution, implementing blockchain and IoT in the pharmaceutical supply chain introduces potential cybersecurity risks. The decentralized nature of blockchain makes it resistant to many common forms of cyberattacks, such as tampering and data breaches. However, this does not make it entirely immune to security threats. For example, 51% of attacks, where a malicious actor gains control over most of a blockchain network's nodes, could potentially manipulate records or disrupt the system. To mitigate these risks, blockchain networks must adopt robust consensus mechanisms and implement advanced cryptographic techniques to ensure that data remains secure (Rauniyar, Wu, Gupta, Modgil, & Lopes de Sousa Jabbour, 2023) [51].

In the case of IoT, the challenge lies in securing the devices and networks that are used to collect and transmit sensitive data. IoT devices are often vulnerable to cyberattacks, particularly if they are not adequately secured or updated with the latest security patches. IoT devices in the pharmaceutical supply chain, such as RFID tags and temperature sensors, must be designed with encryption and secure communication protocols to prevent unauthorized access. Regular software updates and patching are essential to protect against emerging cybersecurity threats (Agarwal *et al*., 2022) [9].

A multi-layered cybersecurity strategy is necessary to ensure the secure implementation of blockchain and IoT in pharmaceutical supply chains. This includes implementing strong encryption, secure access controls, regular system audits, and employee training on security best practices. Blockchain solutions can also incorporate advanced cryptographic techniques, such as zero-knowledge proofs, to enhance security without compromising system performance. Furthermore, organizations must collaborate with cybersecurity experts to continuously monitor for vulnerabilities and respond swiftly to any detected threats (M. C. Kelvin-Agwu, M. O. Adelodun, G. T. Igwama, & E. C. Anyanwu, 2024d) [35].

5. Conclusion and Recommendations

5.1 Summary of Blockchain and IoT's Potential in Combating Counterfeit Drugs

Integrating blockchain and IoT technologies represents a transformative approach to addressing one of the most critical challenges in the pharmaceutical industry: Counterfeit drugs. As the U.S. pharmaceutical supply chain faces increasing threats from counterfeiters, which jeopardize patient safety, cause economic losses, and undermine public trust, blockchain and IoT offer promising solutions that could revolutionize how drugs are tracked and verified throughout the supply chain.

With its decentralized and immutable nature, blockchain ensures that all transactions related to drug movement are securely recorded, creating an indelible trail that all stakeholders in the supply chain can verify. This transparency and traceability are crucial in preventing the introduction of counterfeit drugs, as it enables regulators, manufacturers, wholesalers, and distributors to track the provenance of every drug from production to delivery. Blockchain also allows for smart contracts, which automate compliance enforcement and provide real-time verification of drug authenticity, significantly reducing the risk of fraudulent activities. Blockchain establishes a high confidence level in the legitimacy of the drugs being distributed by ensuring that every transaction is cryptographically validated and timestamped.

On the other hand, IoT technologies, such as RFID tags, NFC-enabled devices, and smart sensors, enable real-time monitoring of drugs as they move through the supply chain. These devices collect crucial data, such as temperature, humidity, and location, that can provide valuable insights into the condition and status of the drugs during transportation and storage. IoT's ability to detect anomalies—such as temperature excursions that could affect drug efficacy or integrity—ensures that only drugs in optimal conditions are delivered to patients. Furthermore, IoT technologies can work with blockchain to enhance visibility and traceability, enabling end-to-end drug product monitoring and ensuring that discrepancies are quickly identified and addressed.

The combined use of blockchain and IoT holds the potential to create a fully secure and transparent supply chain where drugs can be tracked and verified at every stage, from manufacturer to consumer. This improves the safety and quality of pharmaceuticals and reduces the operational inefficiencies associated with traditional tracking systems. However, for these technologies to achieve their full potential, various challenges must be overcome, such as technical scalability, regulatory compliance, and industry adoption.

5.2 Policy and Regulatory Recommendations for Effective Adoption

Several policy and regulatory actions are essential to fully realize the benefits of blockchain and IoT in combating counterfeit drugs. First, regulatory bodies such as the FDA must update and align existing frameworks, such as the DSCSA, to incorporate the use of blockchain and IoT technologies. These updates should include establishing clear guidelines for implementing these technologies within the supply chain, ensuring they meet safety, efficacy, and compliance standards. By recognizing blockchain and IoT as viable tools for improving supply chain integrity, regulators can provide a legal framework that encourages their adoption while ensuring that they adhere to public health and safety standards.

Additionally, policymakers should foster collaboration between regulatory bodies, technology developers, and industry stakeholders to create comprehensive, standardized blockchain and IoT integration protocols. This would involve the development of universally accepted technical standards for data formats, encryption methods, and reporting requirements, which would facilitate interoperability across the entire pharmaceutical supply chain. Standardization is crucial for enabling seamless communication between the stakeholders involved, from manufacturers to distributors to regulators, and ensuring that the technology can be deployed on a large scale.

Incentives, such as tax breaks or grants, could also encourage pharmaceutical companies, especially small and

medium-sized enterprises, to invest in blockchain and IoT technologies. These incentives would help reduce the financial burden of adopting new technologies and accelerate the industry's transition toward more secure and efficient supply chains. Moreover, regulators should actively engage with the industry to raise awareness about the advantages of blockchain and IoT in preventing counterfeiting and provide support in implementing and certifying these technologies.

5.3 Industry Collaboration Strategies for Large-Scale Deployment

For blockchain and IoT technologies to be effectively deployed on a large scale, collaboration among key stakeholders in the pharmaceutical industry is critical. Pharmaceutical companies, logistics providers, technology vendors, regulators, and consumers must work together to create a cohesive and efficient system that leverages the full potential of these technologies. A collaborative approach will help align the goals of each stakeholder, ensuring that the solutions implemented meet the diverse needs of the supply chain while addressing key concerns such as cost, scalability, and security.

Industry consortia, such as those established in other sectors (e.g., automotive and finance), could serve as a model for creating a collaborative platform for blockchain and IoT integration. These consortia would bring together industry leaders, technology experts, and regulatory authorities to develop standards, share best practices, and coordinate the implementation of secure supply chain solutions. By pooling resources and expertise, industry stakeholders can mitigate risks, reduce costs, and accelerate the development of solutions that work across the entire supply chain.

One key strategy for fostering collaboration is the establishment of pilot programs or joint ventures between pharmaceutical companies and technology providers. These pilot programs could be used to test and refine blockchain and IoT solutions in real-world settings, allowing stakeholders to identify potential challenges and improve system design before a full-scale rollout. Involving all relevant parties from the beginning ensures that the solutions developed are practical, scalable, and meet the regulatory and operational requirements of the pharmaceutical industry.

Additionally, international collaboration will be crucial, as the pharmaceutical supply chain is global. By aligning blockchain and IoT standards across countries, regulators and industry leaders can ensure that drugs are tracked and verified consistently, regardless of their origin or destination. This would reduce the risk of counterfeit drugs entering the supply chain from foreign markets and would provide global visibility into drug movements.

5.4 Future Research Directions in Secure and Scalable Blockchain-IoT Integration

The successful integration of blockchain and IoT in the pharmaceutical supply chain is an ongoing process, and continued research is necessary to address existing limitations and explore new opportunities. One area of future research is the scalability of blockchain solutions. As the pharmaceutical supply chain grows in complexity and size, ensuring that blockchain networks can handle vast amounts of data without compromising performance will be critical. Research into more efficient consensus algorithms and the development of hybrid blockchain models that combine the benefits of both public and private blockchains could help address scalability concerns while maintaining data integrity and security.

Another research area is optimizing IoT devices for pharmaceutical supply chains. IoT technologies, such as sensors and RFID tags, must be further refined to enhance their accuracy, reliability, and compatibility with blockchain systems. Researchers could focus on developing advanced sensors that provide real-time data with higher precision and lower energy consumption. Additionally, improvements in the security of IoT devices, including better encryption methods and more secure communication protocols, are necessary to prevent data breaches and ensure that the integrity of the supply chain is maintained.

Interoperability between blockchain and IoT systems remains another critical research focus. Standardized communication protocols and data formats must be developed for these technologies to work seamlessly together. Future research could investigate how best to synchronize blockchain's immutable ledger with IoT's real-time data streams to provide a unified, end-to-end solution for tracking and verifying pharmaceutical products.

Lastly, research should explore the regulatory and legal implications of implementing blockchain and IoT in the pharmaceutical industry. As these technologies are still evolving, regulatory frameworks must be continuously updated to address emerging data privacy, security, and cross-border trade challenges. Researchers could investigate ways to harmonize global regulations for blockchain and IoT technologies to ensure their widespread adoption while ensuring compliance with local laws.

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