State of Blockchain Adoption on the Pharmaceutical Supply Chain Industry Study

Executive Summary – October 2017

The Industry Challenge

Pharmaceutical manufacturers, in collaboration with their trusted partners, have to manage complex supply chains that span across multiple continents with the goal of effectively distributing medicines as efficiently and securely as possible. Securing and optimizing the pharmaceutical supply chain does not squarely rest on the shoulders of one entity; it requires effective collaboration and harmonization with multiple trading partners and regulatory agencies. The logistical complexities of supply chain operations are further exacerbated with the current fragmented, siloed and centralized data systems that create opportunistic threats leading to economic and human costs.

It is well documented that the global counterfeit medicine market is exploding to the point that the World Health Organization (WHO) cannot effectively quantify the size and scope of the problem. Counterfeit medicine is a serious epidemic directly impacting patient safety and global economics.

- The WHO roughly estimates that 10% of medicine worldwide is counterfeit and rises to 30% in emerging regions
- Counterfeit medicines apply to both lifestyle and life-saving drugs
- The WHO estimates that 50% of medicine bought over the internet is fake
- The European Union Intellectual Property Office (EUIPO) estimates €10.2Bn lost annually and 90,000 direct and indirect jobs lost to manufacturers as a result of counterfeit medicine
- The WHO estimates that more than 120K lives are lost each year in Africa from fake anti-malarial drugs

In addition to creating a security gap in the supply chain, the current infrastructure is also inefficient in anticipating drug shortages or drug recalls—it lacks clear visibility into its inventory.

- A survey conducted by Premier Health Alliance (2010) estimated that drug shortages cost hospitals US$200MM as it had to resort to higher cost alternatives
- A survey by the American Society of Health Pharmacists (ASHP) estimated that yearly labor in managing shortages averages about US$216MM nationwide.

For decades, the pharmaceutical industry in collaboration with regulatory agencies have attempted to address supply chain security problems with new policy

initiatives. Policy alone in a digitized world cannot effectively combat the challenges that are a byproduct of legacy platforms that are not equipped to operate in a data-sharing economy. Emerging technologies, such as blockchain, have come to the forefront of the discussion as a means to help the pharmaceutical supply chain effectively secure and optimize its operations.

Blockchain technology is the underlying ledger system for bitcoin transactions. For the past few years, there has been a great deal of discussion and effort to bring blockchain into industrial applications – finance, agriculture, healthcare, energy and more. Blockchain is essentially a decentralized platform that distributes and verifies shared data with trusted partners in a secure, tamper-proof environment. Blockchains offer varying levels of data anonymity depending on the levels of permission and the use of private versus public blockchain applications. For an introduction to blockchain, read "Blockchain Explained" at MIT Sloan School of Management.

The Background
In June 2017, the Institute of Electrical and Electronics Engineers Standards Association (IEEE-SA) hosted the first event exclusively evaluating blockchain technology for securing and optimizing the pharmaceutical supply chain. The Pharma Supply Blockchain Forum in Rockville, MD gathered more than 50 industry representatives including executives from pharmaceutical manufacturers, wholesalers and dispensaries (i.e. retail pharmacies, health facilities, etc), regulators and other stakeholders in the distribution process. The event featured a "white board" session which enabled attendees to voice their perspective on the benefits and challenges of implementing a revolutionizing technology such as blockchain on their supply chain operations. Based on the feedback there were four key points that developed out of the session:

1. Benefit: Blockchain is the ideal technology to comply with the serialization guidelines in the US FDA's 2013 Drug Supply Chain Security Act (DSCSA).
2. Key Question: Who will pay for the blockchain technology?
3. Key Question: Who "owns" the data on the blockchain?
4. Key Question: How to get buy-in from key users and decision-makers to implement?
5. Key Question: What "type" of blockchain model (private vs public) would be of most interest to the respective groups to maximize the benefits of the technology?

The aforementioned key questions became the baseline for a US-based, targeted study on the state of blockchain adoption on the pharmaceutical supply chain. The study is the first of its kind on two perspectives:
1. Unlike most, if not all, blockchain industry studies, this study goes beyond the hype of investment and prioritization and goes directly to qualified executives who are currently in or about to embark on the process of adopting blockchain on the supply chain.

2. The study is targeted and focused to one specific area of the pharmaceutical framework and talking directly to executives who are evaluating the technology and the prospect of proof of concept (POC) and/or project leading a POC or pilot study in their operations.

The Purpose of the Study
The objectives of the research were to identify gaps and barriers surrounding the adoption of blockchain technology. The study aimed to get the perspective of project leaders and decision-makers who are familiar with the technology and are actively exploring or testing the concept for their supply-chain operations. The study was to provide an in-depth perspective on those barriers and to prepare a strategic plan to utilize tools, such as education and awareness programs, and the development of standards to close the gap on barriers as well as to progress toward industry-wide adoption.

The Respondents
The study was independently administered and managed by Ipsos, a globally respected market and opinion research specialist, and sponsored by the IEEE-SA. The online study comprised of 300 US-based, qualified, respondents who completed the questionnaire in August 2017. Qualified respondents' criteria included pharmaceutical industry executive with a baseline knowledge of blockchain applications. The 300 respondents equally represented the key trading partners on the supply chain—31% manufacturers, 34% wholesaler, and 35% dispensaries (ie. retail pharmacy or health facility).

Key Findings and Conclusions

I.   Correlation between awareness and propensity to adoption
The majority of respondents indicated they are "exploring the use of blockchain technology" in their supply chain operations, while some are in proof of concept (POC), and about one in five are pilot study. The study pointed to a direct correlation between "level of familiarity with the blockchain technology" and their company's likelihood to participate in various types of blockchain solutions. Similarly, the more respondents were entrenched—either in proof of concept or pilot study—the more value they found in utilizing the technology.

Respondents who are less familiar with the technology indicated they were less likely to participate on an existing blockchains or even consider investing/building their own.

II.   Benefits and Barriers to Adoption

All three (3) key trading partners indicated they found blockchain technology to be

useful, efficient, valuable and secure. In addition, the trading partners predominantly agreed on the perceived beneficial outcomes of the technology: securing the supply chain, better control of inventory, and verifiable database to record transactions. All key partners clearly indicated perceived blockchains would help them effectively comply with the FDA's DSCSA guidelines.

As it relates to perceived barriers to adoption. wholesalers and dispensaries are more aligned on perceived barriers versus pharmaceutical manufacturers. Both wholesalers and dispensaries indicated acceptance/buy-in of users, challenges of new technology, and connecting to all networks as top three barriers versus manufacturers who indicated cost, security, and connecting all networks/integration as their top three concerns. Stated barriers to adoption of the technology amongst all three groups are the uncertainty of compliance with the FDA when utilizing blockchain, the visibility of the data, and trusting the partner's ability to view company information in an autonomous system. The derived barrier of adoption highlighted a major misunderstanding of the benefits of the technology when all groups indicated "no major financial benefit for implementation."

III.   The correlation between financial investment and data ownership

The majority of the respondents indicated that pharmaceutical manufacturers should have the financial and maintenance responsibility in implementing blockchain, and indicated that manufacturers would assume data ownership on the blockchain. This indicator directly ties back to pharmaceutical manufacturer's concern on the cost of developing the blockchain.

Although the majority of respondents indicate pharmaceutical manufacturers should have to pay for the technology implementation, approximately one-third (1/3) of the respondents indicated that all three trading partners would equally benefit and have "the most to lose" by implementing blockchain. Interestingly, the respondents who are in a POC or pilot study mentioned that manufacturers have the most to gain with the technology, while those who are not, indicated that wholesalers and dispensaries would benefit more.

IV.   Planned Next Steps
The majority of the respondents mentioned that they are 'extremely likely' to progress to the next step of progression and implementation of Blockchain technology within two years. Of the three (3) groups, pharmaceutical manufacturers showed the greatest propensity to advance to the next step.

V.   Conclusions
The main conclusion drawn from this study indicates there is a need for more education for industry stakeholders (business executives, enterprise data

managers, regulators, etc.) at multiple levels—from baseline introduction to advanced principals and understanding.

The main conclusion drawn from this study is the need for more education and development of technical standards to advance the adoption of the technology. First, there exists a significant need for awareness and education at a baseline level on the benefits and outcomes of the technology. Second, for those who are more familiar with the technology, they must be better educated on all of the potential benefits and outcomes beyond just compliance, must have a deeper understanding of trust in a "trustless" autonomous platform, and understand the role of anonymity in a transparent data-sharing system.

The need for technical standards manifests itself in areas where respondents indicated concerns with integrating existing network systems, the costs of implementation, trust in autonomous systems, and obtaining buy-ins/acceptance from users. The development of standards in this area would address some of those barriers as standards are developed and approved through group consensus—a hybrid of technologists, executives, regulators and academia—and certify that the technology is a credible solution for industry application. Standards enable systems to be created systematically, eliminating the need for customization and increased costs and development, while offering guidelines for permissions and usage rights.