Case Study:
The Right Rx for the Pharmaceutical Supply Chain? LedgerDomain’s Hyperledger Fabric Solution
When a patient picks up a prescription from their local pharmacy, there’s a chance the process itself turns into a headache. Four billion prescriptions\(^1\) were dispensed at US pharmacies in 2019 and even conservative estimates\(^2\) suggest that over 100 million prescriptions may be incorrectly dispensed. With that in mind, blockchain solution providers are joining forces with healthcare leaders to put better tools into the hands of pharmacists working to ensure the right drugs reach the right people.

“Despite the best efforts of pharmacists, things slip through the cracks,” says Ben Taylor, CEO of LedgerDomain,\(^3\) an enterprise-grade blockchain solutions provider known for its work on developing the next generation of healthcare and pharmaceutical supply chains. “You’re getting the wrong drug, you’re getting an expired drug, you’re getting someone else’s drug. We’re getting drugs from another country that might not even be approved for use in the U.S.”

It doesn’t help that there is no universal database that serves as an official record for all the medications criss-crossing the United States. Instead, the pharmaceutical supply chain is "a patchwork of traditional databases... an underperforming, old-style, paper-based supply chain," says Taylor.

All of these factors make it exponentially harder to catch human errors\(^4\) and easier for criminals to infiltrate with man-in-the-middle attacks and introduce counterfeits within the pharmaceutical industry.

“Most of the time, problems are discovered before they can reach the patient, but you really don’t know how many fakes are out there because there’s no way to keep bad actors from pranking the unsuspecting,” says Taylor. “That’s why some people last year went to pick up a bottle of Oxycontin and got a bottle of Aleve.”\(^5\)

In 2013, a law was passed to empower the US FDA to “pull the pharmaceutical supply chain kicking and screaming into a more modern era,” says Taylor.

That law, the Drug Supply Chain Security Act\(^6\) (DSCSA), is an ongoing, decade-long effort to track and trace prescription drugs in the United States. The vision is to have an interoperable system that will allow for drug tracing, product verification, and prompt

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— Dr. Scott Gottlieb (then FDA Commissioner)
detection and response protocols to handle all suspect medications. The DSCSA is intended to enhance the FDA’s ability to help protect consumers from drugs that may be counterfeit, stolen, contaminated, or otherwise harmful.

This issue has come to the forefront more urgently as the coronavirus pandemic started ravaging the U.S. healthcare system in 2020. “We have drug shortages and because everybody’s hiding and hoarding their drugs, nobody in the pharmaceutical supply chain is quite sure what’s going on,” says Taylor. “And we’ve been reading more about this with COVID. Supply chain integrity has never been more important.”

As a recent Bloomberg story put it, the supply chain is not ready for a vaccine. “Shippers have struggled for years to reduce cumbersome paperwork and upgrade old technology that, unless addressed soon, will slow the relay race to transport fragile vials of medicine in unprecedented quantities.”

In order to have a successful interoperable system launched by 2023, it was clear the FDA needed a more advanced technology to bring together Big Pharma and all the players at each stage of the supply chain—from manufacturers, repackagers, and wholesale distributors to dispensers—under a single umbrella. (Under the law, this includes all Authorized Trading Partners, or ATPs.) So the FDA turned to the public in 2019 and asked for new, cutting-edge approaches to improve the prescription pipeline.

“Clearly that old Death Star model – my relational database, your relational database, and a fax machine between them – is not going to work. Initially people thought that they might do it with ‘advanced new technology’ like email,” LedgerDomain’s Will Jack chuckles, “That has turned out not to meet their needs.”

“Ultimately,” confirms Taylor, “we needed a real-time collaborative system.”

“How Blockchain Provides the Perfect Dose of Privacy

What was clear to LedgerDomain was that in order to deliver on a collaborative environment that could bring together highly competitive pharmaceutical companies and their distribution partners, “blockchain with its privacy-preserving elements is a great way to do that,” says Taylor.
Hyperledger’s open source community agreed and rose to the challenge. More than a quarter of the proposals that were submitted to the FDA were distributed ledger solutions built with a Hyperledger framework.

LedgerDomain was among them. As a member of the Linux Foundation—which also sponsors the Hyperledger project—LedgerDomain is active in advancing the use of blockchain to drive pharmaceutical supply assurance directly to patients. LedgerDomain is also a charter member of the Clinical Supply Blockchain Working Group, an initiative formed along with Pfizer, Biogen, GlaxoSmithKlein, Merck, UPS, UCLA Health, IQVIA, and other healthcare leaders.

LedgerDomain proposed a blockchain-based solution in collaboration with UCLA and the pharmaceutical company Biogen. (UCLA is also a member of Hyperledger through their Blockchain Lab.) Titled “UCLA-LedgerDomain: DSCSA Solution Through Blockchain Technology,” the proposal centered on the development and live testing of BRUINchain, a blockchain-based system that meets DSCSA standards for pharmaceutical dispensers all within a shared-permission yet private ecosystem.

For BRUINchain, LedgerDomain selected Hyperledger Fabric for its framework because “it’s an open source project with substantial community and enterprise support, so we could build our solution on top of it with full confidence,” says Dr. Victor Dods, LedgerDomain’s chief software architect.

In contrast to open, permissionless blockchains, Hyperledger Fabric was built with governance and privacy at its core. The permissioned authorization structure of
Hyperledger Fabric means that network membership and participation rules may be explicitly defined to match up with the Authorized Trading Partner community. Hyperledger Fabric’s unique encrypted data storage also affords users greater privacy compared to other blockchain solutions because, even though members can confirm and reference transactions, the data remains private between the respective parties of each transaction and can be stored off-chain.

Most importantly, while the pharmaceutical supply chain has numerous stakeholders, LedgerDomain’s Hyperledger Fabric solution establishes one version of the truth for the pipeline that is immutable and invaluable.

This consensus is particularly vital in Big Pharma, as this single record protects the supply chain against double counting and disputes while also surfacing possible instances of counterfeiting, diversion, spoofing, or man-in-the-middle attacks.

“Unlike relational databases, no single user or organization can access the full record of transactions within a blockchain to tamper with transaction data,” says Alex Colgan, head of marketing at LedgerDomain. In addition, after a transaction is struck between two parties, each will have keyed access for later decryption and analysis, as might a regulator or auditor.

“The world’s supply chain isn’t ready for a Covid-19 vaccine.... Shippers have struggled for years to reduce cumbersome paperwork and upgrade old technology that, unless addressed soon, will slow the relay race to transport fragile vials of medicine in unprecedented quantities.”

— Bloomberg

“The Last Mile”

BRUINchain applied these tools to “the last mile” of the supply chain because “the last step in every supply chain is the one where the most error, the most entropy, the most confusion occurs,” says Taylor. “The pharmacy is where the rubber meets the road.”

To bring order to the process, LedgerDomain honed in on the enhanced requirements for package-level tracing and alerting that comply with DSCSA regulatory checks. Then the team tested their product within UCLA Health’s network of 500 pharmacists and technicians, focused on tracking the drug Spinraza,¹³ the first medication approved to treat children and adults with a rare and often fatal genetic disease called spinal muscular atrophy.
The cost of one dose? Try $125,000.

“To the untrained eye, it looks like water,” says Taylor. “So one could envision criminals easily spoofing a transaction and introducing a counterfeit drug.”

To prevent that from happening, everyone from the receiving bay to the patient’s caregiver at UCLA Health used the BRUINchain mobile app to scan the unique 2D barcode on each dose of Spinraza as the drug made its way through the distribution process. “This makes it possible to track the drug from the stockroom to the pharmacy ,” says Taylor. “With every transaction logged on the blockchain during its journey, the drug must pass a series of DSCSA-defined checks so it can be administered to the patient with confidence.”

The single barcode scan tracks data such as expiration date, verifies the barcodes with the manufacturer, and confirms that a human expert had inspected the drug for quality assurance. The use of barcodes in pharmacies has been shown to reduce errors by more than 90%.14

The BRUINchain app was such a game changer that “our stakeholders wanted even more tracking,” says Taylor, whose team expanded the app’s capability such that the UCLA team went from having no consolidated picture of their Spinraza stock to checking the app about 100 times in a week for information. “That’s how closely they’re monitoring this drug,” says Taylor. “Doctors now would rather look at the inventory on their iPhone than look in the refrigerator because the BRUINchain app will tell them, with the help of Hyperledger, was this already verified by Biogen? Is the expiration date good? Is it a good drug? Is it ready to go? All that information is right at their fingertips, instantly.”

LedgerDomain assigned a six-member team to design, develop, and test the BRUINchain system over six months. On the frontend, there’s a mobile application, which is also called BRUINchain, that is built using commercial off-the-shelf technology. Logging and analysis was achieved with Splunk, a platform for searching, monitoring, and analyzing machine-generated big data.

But the team also developed new enterprise products along the way. The biggest challenge engineers faced was effectively interfacing with the manufacturer serialization teams to verify products. In the end, the automated verification system Oraculous Notification Service was created to serve the role of “blockchain oracle,” allowing interoperability between the Hyperledger Fabric blockchain app and outside manufacturers without requiring provisioning their membership on the BRUINchain blockchain.
LedgerDomain Selvedge, the world’s first enterprise-grade blockchain application server, paired with DocuSeal, a new privacy-preserving framework for encrypted and immutable file and message sharing, were added to enhance privacy protections for documents and data, and are foundational components of the BRUINchain system.

On the backend, all of this sits on top of a blockchain framework that was built with the 1.1 million lines of Hyperledger Fabric code in addition to Hyperledger Fabric’s private collections feature—all deployed right out of the box.

“With blockchain, we have a transaction record that is tamper-proof, time-stamped, near-real-time, and auditable,” says Colgan. “Hyperledger Fabric makes it possible to deploy a collaborative framework at scale, while preserving privacy and security consistent with the law’s provisions and intent.”

“The Positive Side Effects

Selected by the FDA as part of its DSCSA pilot project program, BRUINchain exceeded UCLA Health and LedgerDomain’s expectations. The BRUINchain app’s barcode scanning functionality on iPhones was 100 percent effective, and the Hyperledger Fabric-based system was able to track every dose of Spinraza at UCLA Health, down to which refrigerator each dose was stored in across the campus.

According to the FDA, the time it takes to physically fill out Form FDA 3911—an essential document used to notify the FDA and all immediate trade partners within 24 hours of an illegitimate or suspect product—is estimated to be an hour, which includes the time to review instructions, search existing data sources for answers, gather and maintain the data needed, and complete and review the information.

By automatically sourcing information for all of the form’s required fields through the blockchain, BRUINchain’s response time to deliver and exchange the same information has been drilled down to a mere 50 millisecond latency, says Colgan. “BRUINchain reduces reporting time from an hour to the push of a button.”
The efficacy of BRUINchain also emphasized the need for new and necessary steps for risk management when dealing with compromised drugs in the supply chain. “Our blockchain system helps busy pharmacists flag drugs requiring investigation and quarantine,” says Taylor. With that in mind, high-visibility “quarantine” labels were designed to segregate suspect packages.

This supply assurance does not come without cost. Based on their results, LedgerDomain and UCLA anticipate that the labor, training, and related costs of a real-time DSCSA-compliant system would amount to 13 cents per dispensed prescription. However, without blockchain in place to power real-time single-scan verifications, the team calculated that the price would be 17 cents. In other words, blockchain could save the industry over $180 million per year in direct costs – but that’s just the tip of the iceberg.

“From a dispenser’s perspective, the DSCSA checks will be expensive and we want to get value from this process,” said Dr. Will Chien, one of the UCLA Health pilot leads. “Even more, we don’t want drugs to pile up while we are waiting on verification, so the verification should be nearly real-time.” With more precise inventory management and near-real-time verifications in place, pharmacies could avoid the need to hold excessive safety stock pending verification, saving $1.4 billion each year.

“A Possible Cure for the Drug Supply Chain

On the heels of the successful pilot, LedgerDomain is continuing to expand on the program, testing a scalable implementation with many more medications and nodes in a recent virtual technology summit. Over the course of 138 hours, their Hyperledger-based framework proved capable of handling 50 million drug uploads on a single server, which equates to over 100 transactions per second. In addition, LedgerDomain demonstrated a new iPhone app that allows users to scan the 2D barcode on any prescription drug in the United States and instantly access up-to-date information. This master data management app is capable of, including recalls, extended expiration dates and up-to-date package inserts.

“We see blockchain as the ‘honest broker’ that will allow hundreds of competing pharmaceutical and biotech enterprises and their vendors to work collaboratively and

— Ben Taylor, LedgerDomain
communicate with hundreds of wholesalers and tens of thousands of dispensers,” says Colgan.

A blockchain solution adopted by Big Pharma and supported by each company’s respective ecosystem will not only make the drug dispensing process more seamless; it will also help protect patients in the long run.

Now more than ever, this is a key concern in health care as coronavirus cases continue to rise across the U.S. in 2020. “Much of our work on real-time supply chain assurance in particular is taking on renewed focus amid the COVID-19 pandemic,” says Colgan.

Blockchain could be the therapy the pharmaceutical world needs. In 2019, then-FDA Commissioner Dr. Scott Gottlieb said “we’re invested in exploring new ways to improve traceability, in some cases using the same technologies that can enhance drug supply chain security, like the use of blockchain…. We’re committed to staying at the forefront of new and emerging technologies and how they might be used to create safer, smarter and more trusted supply chains to better protect consumer safety and ensure the integrity of the high quality of products they deserve.”

“BRUINchain successfully met all our DSCSA pilot objectives: from reading real barcodes with a working app, to enabling real pharmacists and real doctors to bring life-saving medicines to the patients that needed them,” says Dr. Chien.

“We’re still just scratching the surface in terms of further downstream benefits of blockchain,” says Taylor. “With selective access to aggregate data, stakeholders might mitigate potential drug shortages. Sensitive gene therapies and personalized medicine could be more easily tracked on their way to individual patients. Ultimately we’re looking at a supply chain that is faster, more efficient, more flexible, and better equipped to handle shocks like COVID.”

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About LedgerDomain
LedgerDomain was founded in 2016 to leverage new blockchain technologies to bring the sophisticated transactional algorithms and platforms used on Wall Street to enterprises all over the world. Building on LedgerDomain Selvedge, the world’s first enterprise-grade blockchain app server, they created a GDPR-compliant framework for encrypted and immutable file and message sharing. This empowers rapid, personalized and secure transactions for industries ranging from pharmaceutical supply, banking, and more.

About Hyperledger
Hyperledger is an open source collaborative effort created to advance cross-industry blockchain technologies. It is a global collaboration including leaders in banking, finance, Internet of Things, manufacturing, supply chain, and technology. The Linux Foundation hosts Hyperledger under the foundation. To learn more, visit https://www.hyperledger.org/