Supply-Chain-Integrity Blockchain Solution for Healthcare

1 Summary

RMTM has devised a suite of solutions using blockchain technology that addresses the second goal stated in the Executive Summary of the Nationwide Interoperability Roadmap: "The nation needs an interoperable health system that *enables providers and communities to deliver smarter, safer, and more efficient care*." Specifically, RMTM uses blockchain to enable the medical supply chain (pharmaceuticals, non-prescription medications, and medical devices) to collaborate to remove counterfeit and sub-standard products from the supply chain, before they become a public health issue.

2 The Need

The need for RMTM's solution emanates from the public health issues that arise not only from counterfeit and substandard products, but also from collaboration issues that keep firms in the industry from working together. Additionally, there is a need for records that can endure the life-cycle of long-lived products. Our blockchain approach address all three of these issues.

Public Health Issues

The current supply chain is dangerous to the nation's health, as evidenced by lawmakers promulgating the Drug Supply Chain Security Act.. The ineffectiveness of counterfeit and substandard products not only keep patients from recovering from various health maladies, but the compositions of such products often create additional health issues of their own. This increases the cost of health care because additional treatment is then required to address both the degraded health of patients who have failed to receive their properly prescribed treatment as well as the new health issues brought on by these counterfeit and substandard products. In fact, the use of counterfeit pharmaceuticals alone is responsible for more than one million deaths each year globally.[1] RMTM's blockchain solution can significantly reduce this impact.

Industry Collaboration

One of the primary reasons that the industry has failed to develop an effective solution to stop counterfeiting is that the most effective solutions require sharing of the crown jewels of competitive data: their purchase and sales transactions. Firms justifiably fear exposing this competition-sensitive information to allow for a tracking through the supply chain of products (for both prescription and non-prescription medications) and components (for medical devices). Exposing this information to competitors makes distributors vulnerable to both disintermediation and makes manufacturers vulnerable to alerting competitors to profitable sources and lucrative products.

Understandably, many industry firms are highly resistant to the efficient collaboration necessary to detect counterfeit and substandard products rapidly in the supply chain. As a result, such products are typically detected only after a public-health issue manifests.

Immutable Record

Because of the requirement to maintain lengthy historical records of products to detect counterfeit and substandard products, it is also critical to have an immutable, scalable record.

3 A Blockchain Solution

The blockchain efficiently address all three of the needs stated above. By creating a blockchain-based, chain-of-custody log to track all of the transactions of each individual product (medication or equipment components), we can verify the provenance of any items being tracked. This solution also allows us to identify the party responsible for introducing counterfeit and substandard products into the supply chain.

The blockchain allows us to record this transaction log. The encryption inherent in the blockchain contributes (though it is not, by itself, sufficient) to the privacy of "crown-jewel" transaction data. And the encryption also creates an immutable historical record

How It Works

The solution has two versions. The first detects counterfeit and diluted finished products. The second detects the incorporation of substandard components/ingredients in the production of both medical devices and medications.

Counterfeit Product Detection

To proactively identify counterfeit, gray-market, and substandard products in the supply chain. RMTM records all transactions in the immutable blockchain ledger. This results in the creation of an encrypted, tamperproof, and non-repudiatable chain-of-custody log. A front-end system can send alerts whenever any party ships more of a product than it legitimately owns. If Vendor A purchases 10 units of product, he can only sell 10 units of product before the system sends out an alert. As soon as he sells more than 10 units, the system issue an alert. Alerts can be sent to buyers, regulators (e.g., FDA) and law enforcement.

The solution offers industry the following benefits:

1. It can provide real-time disclosure of the entire product path both up or down the supply chain.
2. *Dynamic Detection*™ technology proactively discovers suspicious transactions, alerting the FDA when the transaction occurs. (This may be weeks before a public-health incident occurs.)
3. All data are encrypted before being added to the system to keep data safe from prying eyes.
4. The solution architecture limits access to the data themselves. The only access is through pre-formulated queries that generate results in pre-formatted reports. And even this access limits industry firms to viewing only transactions in which they were a party (buyer or seller). Furthermore, even the FDA is limited in its query capability to prevent an insider from querying vast amounts of data to sell or expose.

RMTM achieves these benefits through the use of three innovations:

1. Standard blockchain technology creates a non-repudiatable chain-of-ownership log
2. Proprietary solution architecture for which RMTM is seeking patent protection (provisional application submitted last August) prevents deciphering the log
3. Proprietary cost reduction blockchain verification technology for which RMTM is seeking patent protection (anticipate filing in August).

The solution has been architected and designed. Phase I development focuses on a prototype to demonstrate the solution feasibility to clients in a wide variety of industries.

Substandard Component Detection

To proactively detect substandard components or ingredients, the solution begins by requiring a certification that such components/ingredients fully comply with specifications. This can be a self-certification or a third-party certification depending on the criticality of the certification and the anticipated credibility of self-certification.

The certified parts are then tracked through the supply chain on a quantity basis.

Even though the certification may not be attachable to each individual component or ingredient, the ability to track quantities removes the incentive to misrepresent products in the same way as described above for counterfeit goods.

Detailed Description of the Solution

Tracking the path through which a drug propagates through the system is merely a matter of using the transaction data to create a giant input-output table which includes a series of counters for every member of the supply chain to track their inventory of every product that they handle as illustrated in Figure 1.

In Step 1 of the figure, a manufacturer commissions 300 units of a new product. All downstream counters are at 0 because they have no inventory of the new product.

In Step 2 of the figure, the manufacturer sells 200 units of the product to Distributor A and 100 units to Distributor B. Accordingly, his counter decrements to zero and the 300 units are now spread among Distributors A and B.

In Step 3 of the figure, Distributor A and Distributor B sell all of their product to Dispensers D, E, F, G, and H. Each transaction updates the blockchain database and the entire dispersion pattern of the drug (via the counters) is updated with each transaction. This allows "the system" to know where all of the product is at any point in time. This not only allows regulators to track the path of any product back through the supply chain, but it also allows for the ability to trace forward to identify all holders of the product in the event of a product recall. In a recall, the manufacturer can submit a notice to "the system" and it will propagate the notice to all identified holders of the drug in near-real-time without the manufacturer having to be granted visibility to his supply chain downstream of its own customers.

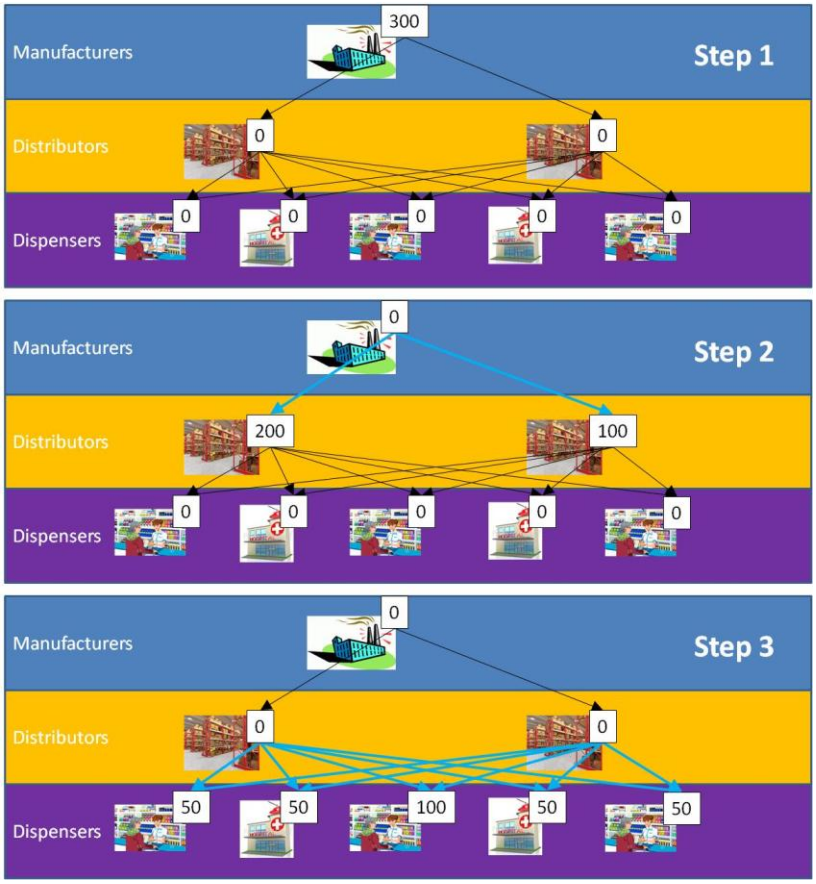

Figure 1: Change of Ownership Tracking. By tracking the input and output flows from each member of the supply chain, "the system" is able to maintain visibility of the path of dissemination of any particular product to recognize which parties have how much inventory. But individual supply-chain members can only see their immediate upstream and downstream transactions.

Dynamic Detection™ Detailed

A particular advantage of this solution is *Dynamic Detection*™: the ability to dynamically identify suspicious transactions as illustrated in Figure 2.

In this figure, Steps 1 and 2 are identical. But in Step 3A we highlight Distributor A's attempt to introduce counterfeit, gray-market, or diluted product into his downstream supply chain. The transactions to Dispensers D, E, F, G, and H occur in the order of time. By the time the Distributor has sold 50 units to the first four Dispensers, his inventory is at zero. He no longer has product to ship to Dispenser H. Accordingly, this transaction will be flagged.

It could well be the case that the product shipped to Dispenser H is legitimate and that the Illegitimate product was shipped to a different Dispenser. But as soon as the Distributor A tries to sell more than he has, all his transactions of the product become suspicious and the FDA and/or law enforcement can be alerted.

One of the benefits of this solution is that it can be configured to prevent the last transaction from occurring. In this way, there will be no way for Distributor A to even attempt to create a paper trail in which he sells more than he has. This further reduces the incentive to cheat. For, even if he purchases Illegitimate products, he will never be able to sell more product than the amount of legitimate product he

has purchased. Assuming, for simplicity that he possesses 200 legitimate units of a product that he sells for $10 each, he will never be able to receive more than $2000 ($10*200 units). If he sells 100 legitimate packages and 100 Illegitimate product packages, he will receive the same $2000 and have another 100 legitimate units in inventory. But he will be unable to sell these because as soon as he tries to sell unit 201, the transaction will be flagged. The legitimate product will be left to expire in inventory.

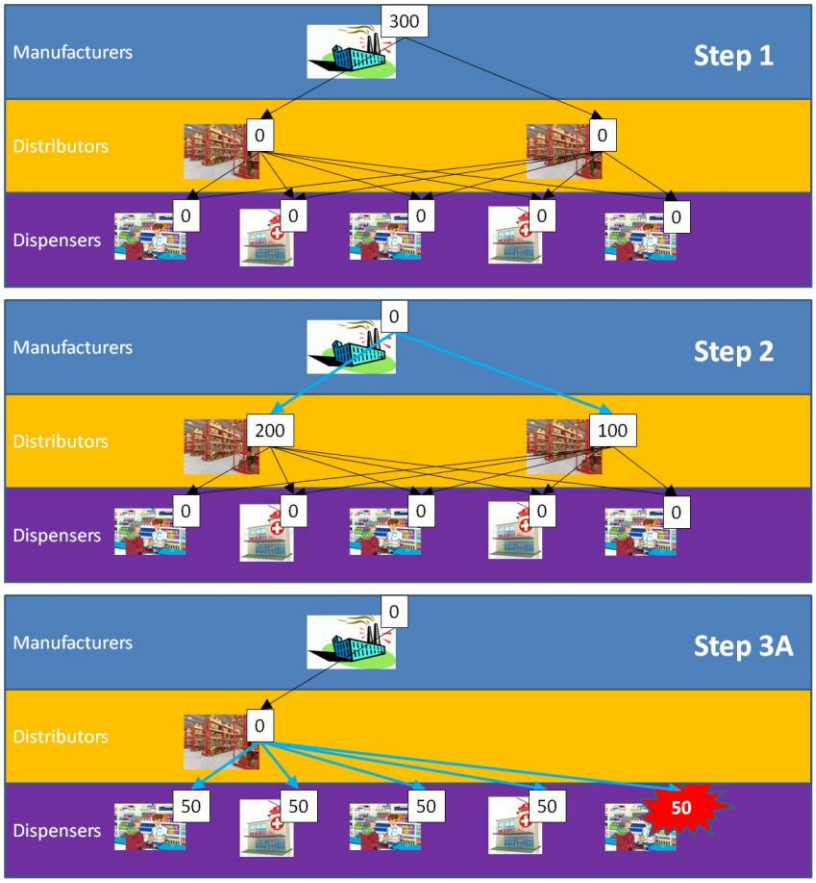

Figure 2: As soon as Distributor A sells more products that he has purchased, as alert can be sent to the FDA, the buyer and/or other applicable law enforcement.

Serial Number Independence

Another benefit of the solution is that it is not dependent on serial numbers. Because the system is based on volume, it can detect Suspect product transactions even when they use legitimate (counterfeit) serial numbers. This diminishes the importance of randomizing serial numbers. If a counterfeiter creates products with legitimate numbers, he cannot introduce them to the supply chain without creating a surplus of product. If Distributor A duplicates the serial numbers in his inventory and sells legitimate product to one Dispenser and Illegitimate product to another Dispenser with the same "valid" serial numbers, the transactions will be flagged for exceeding his inventory or legitimate product.

Imprecise Serial Numbers

This volume basis also accommodates the difficulty that manufacturers and repackagers may have in "certifying" the precise serial number contents once aggregated into cartons and/or pallets. The solution is robust enough to allow the serial number data included in a transaction reference a batch of serial numbers. As the cartons are broken down while the products traverse the supply chain, the system can even replace the batch reference with specific numbers.[2]

Economics

As a shared solution managed by a Solution Provider, the costs of the new solution can be spread across the entire supply chain, making it cost-effective. And as a shared solution, fixed pricing can be established for each supply chain member. And this pricing can be tiered so that larger companies with more products and more transactions can be placed in one tier while smaller firms can be placed in another to ensure fairness and enhance participation. An Independent Administrator defines the rules for pricing. This may mirror the current industry model illustrated by the SAFE BioPharma Association which manages the identity credentialing process for the industry on a global basis.

Implementation

The solution described above has two gaps. The primary gap to be addressed in the solution is a gap in the capabilities of the blockchain is maintaining the confidentiality of transaction data stored in the system. A second gap is the need to stand up an independent administrator to provide governance.

Confidentiality

A top priority for the members of the supply chain is ensuring the confidentiality of the proprietary transaction data that is contributed to the database for track-and-trace purposes. The solution achieves this, in part, through blockchain encryption. Each transaction recorded in the system is digitally signed by both the seller and the buyer. Once each party reviews and agrees that the transaction is accurate, the transaction is added to a block which, in turn, is added to a new version of the encrypted blockchain.

Security Gap

This traditional blockchain approach is not enough to ensure privacy of the information. The one-way hashes used to hide the identity of anonymous parties in blockchain transactions such as Bitcoin do not provide sufficient obfuscation to prevent the re-identification of supply chain members using inference. For example, since Pfizer is the only legitimate manufacturer of Viagra, all transactions commissioning Viagra could be inferred to emanate from Pfizer. The resulting hashed identity could then be presumed to be from a Pfizer agent without having to decrypt the hash.

Closing the Security Gap

RMTM has developed an architectural solution for this problem. Once data are appended to the encrypted blockchain, it is closely held. Unlike the public ledger of Bitcoin, our data can be viewed only for audit purposes by authorized independent auditors selected by the Independent Administrator.

For other users, data will only be obtainable through standardized reports. Users do not directly touch the database after approving and digitally signing a transaction. The Independent Administrator establishes the format for reports and the rules of access that limit who can obtain reports on particular transactions. Reports limit industry members to accessing data only for which they were one of the transacting parties (except for a report providing the name of the ultimate manufacturer of a particular package).

The database is also replicated after every transaction in multiple private locations. This not only reduces the possibility of data loss due to disaster, it also means that a hacker -- were he able to interpret the encrypted data -- would have to simultaneously make the same changes to multiple versions of the database to propagate bad data. Because the database Is being updated continuously, this is unlikely.

Governance

The solution also calls for an independent administrator to manage the governance of the solution. This includes change management, as regulations evolve and the solution is spread to other countries. (Because many major pharmaceutical manufacturers operate globally, they have an incentive to participate in a single solution that can support their global operations. The alternative could compel them to support a wide array of solutions - unique to each national/regional market -- increasing both cost and complexity of compliance.

Evaluation

Potential of the overall concept to help foster transformative change in the culture of health IT

RMTM's solution provides measurable benefits to the public health. These include:

1. a reduction in the number of deaths resulting from bad drugs and bad equipment
2. a reduction in the number and extent of public-health incidents prompted by counterfeit or substandard products
3. a reduction in the billions of dollars spent on counterfeit or substandard products

Viability of the proposed recommendations

We have already performed extensive proofs of concept to ensure that our approach is viable. These include the following:

1. configure, launch and maintain a private permissioned blockchain network
2. manage blockchain client accounts
3. register new serialized products and meta information
4. integrate 3rd party master data sources
5. validate transaction based on product status, availability and history
6. record a multi-signature transaction between participating parties
7. provide query ability for quick lookup, verification and other reports
8. provide data capture API for integration with networked devices (video barcode scanners, smartphones, etc) (IoT)
9. provide consumer facing front-end for analytics and client administration.

Innovativeness of the approach

Our approach not only leverages the capabilities of the blockchain to provide an immutable chain-of-ownership log for the supply chains of the pharmaceutical and medical instrument markets, but we advance the capabilities of blockchain technology with our own enhancements.

Our first enhancement adapts the blockchain -- which was initially developed to support a single, fungible, virtual asset -- to a system capable of supporting multiple, unique, physical assets at huge scale. This is a non-trivial improvement because the native blockchain lacks the indexing of an SQL database or a query language. We have devised a method to rapidly query the blockchain during each transaction to determine whether it is a suspicious transaction.

A second enhancement is our architecture (patent pending) which keeps the blockchain data away from prying eyes of everyone except auditors, to ensure it remains confidential.

A third enhancement (also patent pending) is our high-speed, low-cost consensus approach that allows us to scale to the billions of transactions that occur in the pharmaceutical and medical device industries.

Compliance with ONC Goals

RMTM's blockchain solution aligns with ONC goals as described below.

Strategic Goal 1: Strengthen Healthcare

Our blockchain solution meets the following objectives of Strategic Goal 1:

1. **Objective B: Improve health care quality and patient safety**

By facilitating the removal of counterfeit and substandard products from the market, the blockchain solution helps ensure that products (both medications and equipment) are effective and safe.

2. **Objective D: Reduce the growth of health care costs while promoting high-value, effective care**

The blockchain solution reduces losses to manufacturers stemming from counterfeit and substandard products. This could save up to $200 billion annually in the pharmaceutical industry alone. This savings could be used to reduce the cost of products or be applied to the development of new products to improve the effectiveness of health care

3. **Objective F: Improve health care and population health through meaningful use of health information technology**

The blockchain solution leverages IT to provide improvements to the public health.

Strategic Goal 2: Advance Scientific Knowledge and Innovation

Our blockchain solution meets the following objectives of Strategic Goal 2:

1. **Objective A: Accelerate the process of scientific discovery to improve health**

RMTM's blockchain solution leverages leading edge blockchain technology, supplemented by RMTM's own patent pending innovations to improve public health.

2. **Objective B: Foster and apply innovative solutions to health, public health, and human services challenges**

Blockchain technology is innovative which is why this competition has been fostered.

3. **Objective C: Advance the regulatory sciences to enhance food safety, improve medical product development, and support tobacco regulation**

The same approach used to track the provenance and composition of medications and medical instruments can be applied to food products. And RMTM's *Dynamic Detection*™ simplifies regulator's work by proactively alerting them to suspicious transactions, rather than waiting for a public health crisis to bring the issue to their attention.

Strategic Goal 3: Advance the Health, Safety, and Well-Being of the American People

Our blockchain solution meets the following objectives of Strategic Goal 3:

1. **Objective B: Promote economic and social well-being for individuals, families, and communities**

By removing the economic incentives to provide counterfeit or substandard products, patients don't waste money on dangerous or ineffective products and complications from such products are removed as a public health benefit.

2. **Objective F: Protect Americans' health and safety during emergencies, and foster resilience to withstand and respond to emergencies**

By proactively removing counterfeit and substandard products from the marketplace, public health and safety emergencies are reduced. Furthermore, with a reduced risk of such products being used to address emergencies, the capacity to respond to them is improved.

Strategic Goal 4: Ensure Efficiency, Transparency, Accountability, and Effectiveness of HHS Programs

Our blockchain solution meets the following objectives of Strategic Goal 4:

1. **Objective B: Enhance access to and use of data to improve HHS programs and to support improvements in the health and well-being of the American people**

Rather than relying on expensive sensors and investing in feet-on-the-street to randomly sample products searching for counterfeit or substandard ones, RMTM's solution relies completely on data (purchase and sale transactions) to proactively identify suspicious products in the supply chain. In many cases such products will be identified before they every reach the public and become a public health and safety issue.

Compliance with Nationwide Interoperability Roadmap

RMTM's blockchain solution complies with the goals of the Nationwide Interoperability Roadmap as follows:

1. **2015-2017: Send, receive, find and use priority data domains to improve health care quality and outcome.**

Using transaction data from the supplies chains for pharmaceutical and non-prescription medication makers, as well as those of medical devices, we remove the economic incentive to produce counterfeit or substandard products. This, in turn, reduces the likelihood that such products will continue to wreak widespread havoc on public health and safety.

2. **2018-2020: Expand data sources and users in the interoperable health IT ecosystem to improve health and lower costs.**

The proposed solution improves health both (1) by ensuring that appropriate products are used to care for people and (2) by reducing the public-health impacts caused by side effects of substandard products. Furthermore, the solution directly targets a problem that costs the American public $200 billion annually.

3. **2021-2024: learning health system, with the person at the center of a system that can continuously improve care, public health, and science through real-time data access.**

Patients could access the system to verify the provenance and quality assurance of treatments that they are about to use.

Eligibility

RMTM's compliance with the eligibility criteria of the solicitation is summarized in Table 1.

Eligibility Criterion	Compliance	Notes
1. Shall have registered to participate in the Challenge under the rules promulgated by the Office of the National Coordinator for Health Information Technology.	√	
2. Shall have complied with all the stated requirements of the Blockchain and Its Emerging Role in Healthcare and Health-related Research Challenge .	√	
3. In the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States, and in the case of an individual, whether participating singly or in a group, shall be a citizen or permanent resident of the United States.	√	Incorporated in Pennsylvania
4. May not be a Federal entity or Federal employee acting within the scope of their employment.	√	RMTM is a private subchapter S corporation
5. Shall not be an HHS employee working on their applications or Submissions during assigned duty hours.	√	Employed solely by RMTM
6. Shall not be an employee of the Office of the National Coordinator for Health Information Technology.	√	Employed solely by RMTM
7. Federal grantees may not use Federal funds to develop COMPETES Act challenge applications unless consistent with the purpose of their grant award.	√	This work is not funded by any Federal grants
8. Federal contractors may not use Federal funds from a contract to develop COMPETES Act challenge applications or to fund efforts in support of a COMPETES Act challenge Submission.	√	This work is not funded by any Federal contracts

[1] Source: Interpol See Insight Crime: http://www.insightcrime.org/news-briefs/counterfeit-drugs-kill-1-million-annually-interpol

[2] In current practice in the US, this is not likely to happen because DSCSA does not require final sales by Dispensers to be recorded. This is the only place where specific numbers would be identified.