

Health Law & Business News

# INSIGHT: Blockchain Can Be Ally in Race for Covid-19 Vaccine, Safety

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Using blockchain can help companies involved in developing a Covid-19 vaccine and play a role in ensuring its safety for consumers. Crowell & Moring attorneys look at how blockchain can help with the tracing of prescription drug products through the pharmaceutical supply distribution chain.

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Blockchain can have an impact on the race for a Covid-19 vaccine, increasing product safety and reducing recall expense, and might have helped prevent the recent recall of hand sanitizers because of the use of dangerous ingredients.

In particular, blockchain, a digital, decentralized, distributed ledger that provides a way for information to be recorded, shared, and maintained by a community, can help with compliance with the 2013 Drug Quality and Security Act, which established requirements to facilitate the tracing of prescription drug products through the pharmaceutical supply distribution chain.

It usually takes years before a vaccine reaches mass production from various stages commencing with the exploratory phase, pre-clinical trials, clinical development, regulatory approval to production, and distribution. During these phases, there must be continuous quality control and monitoring of efficacy of the vaccine.

The benefits of using blockchain are that it enables almost instant settlement of recorded transactions, removing friction and reducing risk; is reliable and resilient to outages and attacks; and is transparent, irreversible, and immutable. It is nearly impossible to make changes to a blockchain without detection, reducing opportunities for fraud.

Blockchain can be used in these phases as follow:

- **Exploratory phase:** Blockchain be used to share time-stamped, tamper-proof evidence of success (or failure) of a potential vaccine.
- **Pre-clinical phase:** The authenticity of the blockchain ledger provides one immutable shared source of “truth” for development where biotech and pharmaceutical firms can collaborate about their findings in a secure way for the greater good.
- **Clinical development phase:** When testing on humans is performed, blockchain provides an immutable and trusted mechanism to track informed consent of volunteers (which can be done without revealing personally identifiable information) and the results (including production of immunities and side effects) can be provided to relevant agencies such as the Food and Drug Administration for approval or rejection of the vaccine.
- **Regulatory approval:** Government agencies can actively monitor clinical trials on blockchain.
- **Production and distribution:** Blockchain’s use in supply chain management can make the manufacturing and distribution process more efficient and reduce counterfeiting problems as described below, instilling trust in consumers.

### Product Safety, Reducing Recall Costs, Protecting Brands

Recent problems in the market for hand sanitizer—where methanol, or wood alcohol, a toxic compound that can cause severe adverse health events, was substituted or mixed into certain products instead of the authorized active ingredient, ethyl alcohol—illustrate the potential benefits of blockchain.

Plagued with poor product traceability, the FDA was forced to direct broad recalls of all products made by manufacturers with contaminated products. Better visibility into the supply chain might have alerted distributors and retailers of this problem sooner, and enabled them to more narrowly target the products that posed a risk.

The traceability demanded by regulators, like the Consumer Product Safety Commission and the FDA, aligns directly with the benefits of blockchain. Yet, blockchain can go farther to provide visibility into the component parts and raw materials introduced through the supply chain.

Using blockchain technology for supply chains increases the end-to-end visibility of the products by bringing suppliers and manufacturers together on a single platform. In the case of a defective product that needs to be recalled, the faulty product can be identified and marked on the ledger by the manufacturer. The ledger helps the manufacturer identify affected batch(es) of products, identify the exact supplier, and thus plan the replacement of the part if needed and initiate recall.

Since the supplier has a near real-time copy of the ledger, it also gets notified of the defect and then can initiate an investigation into the cause, take the necessary corrective action, and plan to provide replacement of the faulty part. In turn, this minimizes the impact and cost of the recall by isolating only the affected products immediately and allowing for swift action to take place.

Blockchain could help to end the over-expansive, blanket recalls that occur because there is no reliable way to pinpoint exactly which products to recall. It allows companies to isolate specific products containing a contaminated ingredient, raw material or component part, which can and will translate to less waste and reduced costs. Brand reputations are protected and the adverse consequences of a recall are minimized.

### **Barriers to Adoption**

Despite the numerous advantages to using blockchain for supply chain management, various barriers still exist.

These include lack of knowledge and understanding of blockchain; trouble replacing or adapting existing legacy systems; regulatory and legal concerns like data privacy issues, intellectual property, and enforceability of contracts; cost; uncertain ROI; and overcoming lack of trust, as many companies remain skeptical about blockchain.

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