

The Potential of **BLOCKCHAIN** for Herbal Supply Chain Management

By Karen Raterman

With a supply chain as vast and varied as that of the herbal products industry, it is not surprising that transparency and traceability for herbal ingredients have become primary considerations for herbal suppliers and manufacturers. Strides have been made in recent years to increase traceability of herbal ingredients from farm to store shelf, but ingredients may still become compromised, which leaves the industry subject to potential negative publicity and reduced consumer trust.¹ In this context, some people believe that the industry standard of trust and verification could benefit from an emerging technology known as blockchain.

Vulnerabilities in the supply from adulteration and mishandling to overharvesting and substitution are well documented.² Companies that are vertically integrated with captive manufacturing and their own procurement and sourcing often can provide traceability all the way back to farms, but some companies, such as those that work with contract manufacturers, for example, may have more complicated systems of operation.

“Some companies go above and beyond, but a lot of distributors and other companies still have not figured out their supply chain,” said Len Monheit, managing partner for Trust Transparency Consulting (oral communication, March 18, 2019). However, he noted, companies that don’t have their own manufacturing facilities or vertical integration are more likely to have issues with their supply chain.

Many industrywide efforts have tried to identify and address these challenges through knowledge sharing. In 1990s, for example, the American Botanical Council (ABC) initiated the Ginseng Evaluation Program and published information on adulterated products that were labeled to contain “ginseng” (*Panax* spp., Araliaceae). Also in the 1990s, the American Herbal Products Association (AHPA) published herb safety data and labeling guidance in its *Botanical Safety Handbook*.^{3,4} More recently, the ABC-American Herbal Pharmacopoeia (AHP)-National Center for Natural Products Research (NCNPR) Botanical Adulterants Prevention Program (BAPP) was created in 2010 to address the issue of botanical ingredient adulteration in global commerce and has published more than 50 publicly available documents on the topic.⁵

Most recently, the Supplement Safety & Compliance Initiative (SSCI), spearheaded by the Natural Products Association (NPA) with the support of retailers such as GNC, Walmart, Vitamin

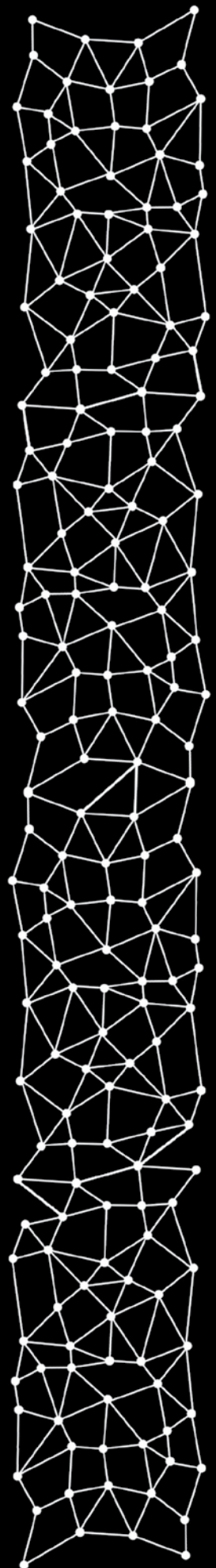
Shoppe, and Whole Foods Market, has worked to develop tools to simplify compliance with good manufacturing practices (GMPs). The SSCI aims to create benchmarks and standardize the collection of supply chain information, while also providing a platform for stakeholder collaboration, knowledge sharing, and networking.⁶

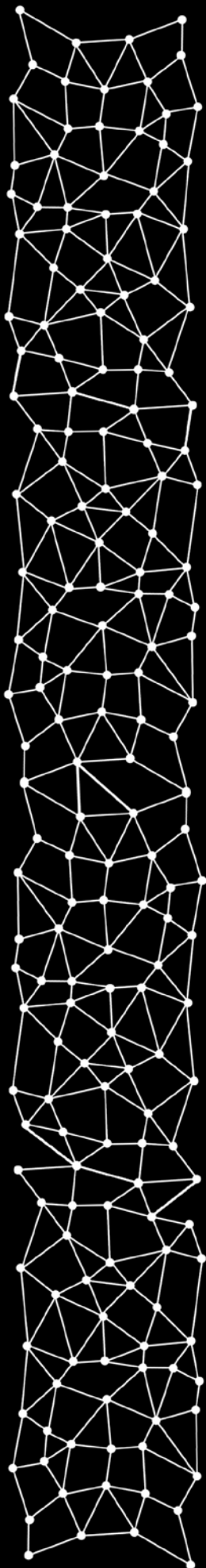
Despite progress, issues remain that leave some to wonder if blockchain could be the missing puzzle piece. There is growing interest in the technology in the herbal products industry, and, according to some experts, it may help solve some of the challenges that companies are facing with respect to tracking ingredients, verifying certifications, and providing transparency and trust in products.⁷ Though no one can predict exactly how this situation will play out, many industry stakeholders believe that blockchain is coming — the question is when and how.

What Is Blockchain?

Blockchain technology is actually not new, having first been developed in the early 1990s. Its first widespread application came in 2008, when it was used to trace cryptocurrencies like Bitcoin.⁸ Essentially, blockchain is a public record of transactions, and whenever someone makes a transaction, it is uploaded to a shared network or database. This chain of linked transactions is the blockchain. Because these transactions are stored in a decentralized network, blockchain is considered secure, unchangeable, and even “unhackable,” and experts see it as having the potential to revolutionize supply

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Explaining Blockchain

In simple terms, blockchain is a unique system used to track economic transactions. It is a digital ledger in which “blocks” of data are bound together in a “chain” and secured using cryptography. It is an immutable record of data that is managed by a cluster of computers that are not owned by any single entity. According to some, this technology has the potential to revolutionize supply chain tracking and traceability in various industries.⁸

chain management across many industries.⁸ Blockchain is already seeing adoption beyond the virtual cryptocurrencies to physical supply chains, including those for ingredients in foods and pharmaceuticals.

In general, blockchain is seen as offering a number of important advantages. It is transparent, secure, and provides a digital, streamlined process for consistent and speedy data tracking, as well as complex solutions for analyzing uploaded data.⁸ However, it also has disadvantages. It is complex and challenging to learn and use; because it is global in scope, it ultimately requires compliance with international laws and standardization; and it has a network effect, which only gains value if it grows in users.⁸

Peeling Back the Layers

A few herbal companies already are using the technology, but many more have expressed interest in it.

“Blockchain technology will become an integral part of all supply chains, because it allows for secure and immutable information storage,” wrote Wilson Lau, vice president of Nuherbs (email, February 26, 2019). “So everyone is looking into it, from shipping companies, for tracking the containers in which herbs and herbal supplements travel, down the pipeline to retailers who are demanding it. For example, Walmart is mandating that all its leafy greens suppliers upload their data to their

blockchain by September 2019.” The mandate is part of the Walmart Food Traceability Initiative announced in 2018, which is designed to increase transparency in the food system and create shared value across the leafy green supply chain.⁹

Blockchain does not necessarily replace any technology that has come before, but it is a new way of doing things, said Gary Nowacki, CEO of TraceGains, a cloud-based supplier of compliance and quality management solutions for the food, beverage, and supplement industries (oral communication, March 14, 2019). “Its fundamental premise is that it will take whatever data that you track and store it in a distribution ledger across servers to make the data immutable, so nobody can falsify it.”

Blockchain is gaining interest for tracking physical items in a supply chain, such as a head of lettuce or the salmon one might purchase in a supermarket to verify that it was ocean-caught. However, using blockchain becomes a lot more complicated in a multifaceted supply chain with multi-ingredient products.

“While it may be feasible to track a piece of salmon from the ocean to the supermarket, it is [significantly] more complex to track all the ingredients that went into the formula for a specific [dietary] supplement,” Nowacki said. This would involve many steps, including tracking the field where the botanical harvest took place, all the people who touched it or transported the ingredient, the packing, processing, and compounding

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facilities, and potentially any temporary ownership by a broker, importer, or distributor. “Then you would have to do all of that for all the other ingredients that went into that capsule,” Nowacki said.

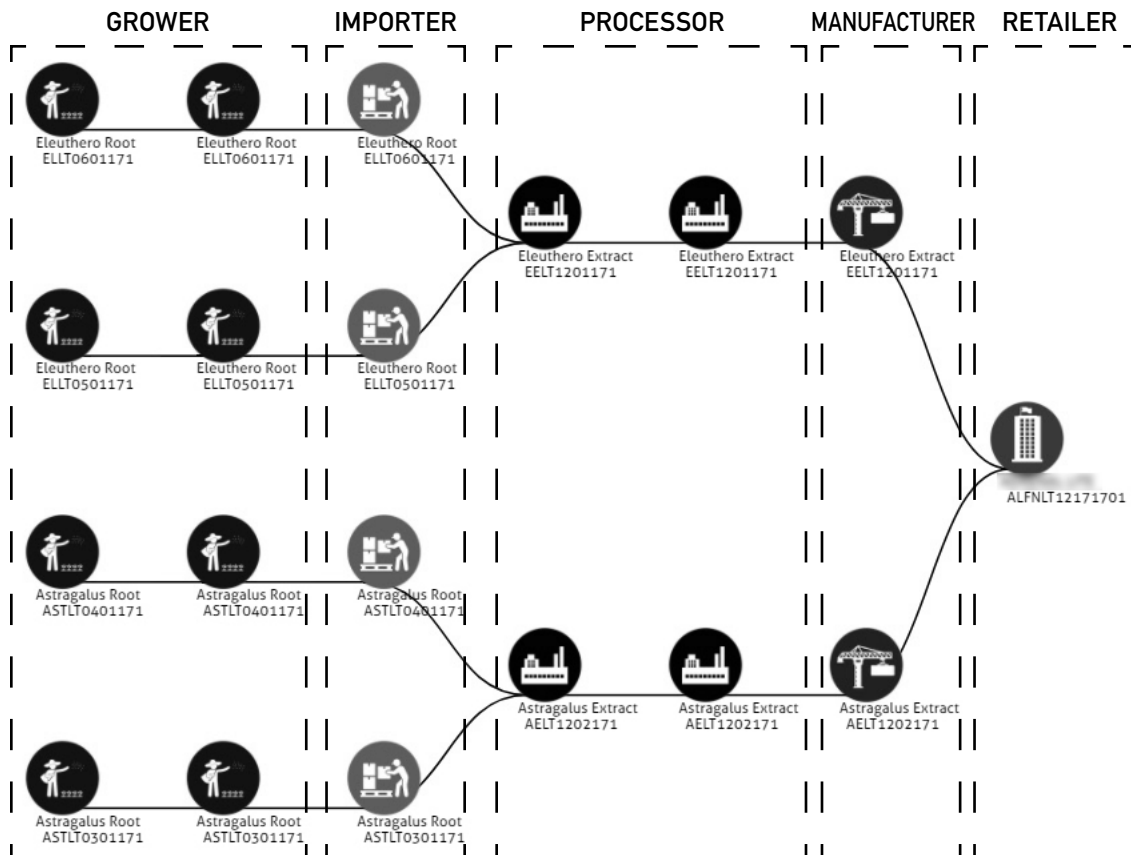
A recent paper from the University College London School of Pharmacy and the University of Westminster School of Life Sciences in London explored the role of blockchain systems in high-value botanical supply chains. The authors of the paper note that the technology may help provide sustainable sourcing and quality assurance and tackle supply problems for complex multi-herb preparations.¹⁰ According to the paper, in these supply systems, there are specific and unique concerns due to the core characteristics of the botanical supply chain. For example, raw materials can be wild or cultivated; a large number of primary producers use very small quantities of raw materials; middlemen often link international purveyors of herbal ingredients; regulations vary in markets around the world;

and some involved parties lack knowledge about threatened or overharvested species. According to the authors, these factors lead to concerns regarding “equitable benefit sharing, responsible sourcing and sustainable supply as it relates to protected or threatened environments.”

The UK paper suggests that blockchain systems, particularly closed systems, address some of these challenges by providing a safe and trusted platform for interaction without the need to build trust among individual parties, and it may also help save time and money by eliminating the need for third parties to mediate disputes.¹⁰ “It is a big onion with lots of layers,” said Sara Newmark, vice president of social impact for MegaFood, which has documented connections with its suppliers both locally and internationally. “It is very complicated at times to understand each and every aspect of our supply chain,” she added.

Some companies that already have strong supply chain traceability in place are cautiously optimistic about block-

TagOne’s Visual Map provides a visual tracking of ingredients and supplies, from seed to shelf, all blockchain enabled. Graphic courtesy of TagOne.





Key data points are captured and validated using blockchain at each stage of the supply chain. This example shows how turmeric can be tracked with a QR code from seed to shelf. Graphic courtesy of TagOne.

chain. Chinese herb supplier Nuherbs, for example, buys many of its herbs from farmers and wild collectors and interacts closely with facilities to make certain the materials are processed to meet its rigorous specifications and adhere to traditional Chinese medicine (TCM) principles, while applying modern technology to ensure quality.

“Blockchain won’t change or necessarily enhance what Nuherbs currently does, since we already have a lot of insight, from origin to our warehouse, through our work with the growers and wildcrafters of our herbs,” Lau said. “But with blockchain, all information would become fully digitized at all stages and be faster than how it’s done now, which has great potential. Blockchain would give us even more insight in the logistic end of things, specifically where, [by whom], and how it was handled.”

Similarly, because herbal tea manufacturer Traditional Medicinals is buying organic raw materials, it already has traceability back to the field, said Ben Couch, the company’s sustainability manager (email, February 12, 2019). “It is also the case that we are not buying widely traded commodity quality that would be in a mass balance* or generic supply context with multiple supply or process options that would necessitate a distributed-ledger traceability. So it hasn’t been a top priority for discussion compared to the more basic supply and logistics planning we’re focused on.”

However, some companies do see a significant upside. “I am speaking from the framework of a B Corporation and a transparency role,” said Newmark, whose company, FoodState (MegaFood), is a certified B Corporation. “From a transparency standpoint or ethical mission of uplifting

communities and tackling the climate crisis, we have an opportunity to [compose] our supply chain of smaller farmers who can make change happen faster. But the herbal supply chain has multiple layers between the brand and the farm, so we have to have things in place to peel the onion.... Blockchain is definitely providing a lot of opportunity to have the world connect in a way that is very powerful,” she said.

Couch also believes there are strong opportunities in specific supply chains and fair trade premiums. “Certified materials like FSC [Forest Stewardship Council]-certified wood or filter paper could benefit from blockchain, so we could know where the fiber is coming from for annual tracking and long-term risk assessment,” he said, adding that fair trade and FairWild premium spending is not consistently reported by producers up through suppliers and companies. Blockchain could conceivably be used to track these payments so brands could see, for example, where the fair trade ginger (*Zingiber officinale*, Zingiberaceae) came from and what the farmer did with the premium. “This would be in a targeted manner, but certainly if blockchain were more widely implemented by major suppliers, it would enable a much stronger traceability platform, providing some of the UPC/barcode scan-based traceability that brands are rolling out.”

A Customized Option

When it comes to dietary supplements and herbs, the challenges remain endless, according to Anand Swaroop, PhD, FACN, president of Cepham, a manufacturer of

* A mass balance system is one in which a producer can obtain a fair trade certification for a specific ingredient, even though it may be mixed with conventional ingredients at the factory level.¹¹ It allows manufacturers, brands, and retailers to support the field impacts of certain certifications without the need to change manufacturing processes to comply with the requirements of a segregated supply chain.¹²

"When we started, we were taken aback by what was happening when it came to the approach of sourcing ingredients. We estimated the lack of transparency at between 90% and 95% for ingredients coming from outside of the United States."

herbal ingredients that claims to have been one of the first companies in the herbal products industry to employ a blockchain solution to its supply chain management (oral communication, February 15, 2019).

Cepharm is using the TagOne Farm to Aisle supply chain transparency solution, with a blockchain platform that was custom-designed for the dietary supplement space as a co-innovation initiative with Dreamweaver LLC, with the input of industry stakeholders through the SSCI effort. TagOne was put into complete operation in 2018, and the system is now online with visibility of the data backed by blockchain. "There were a lot of pitfalls, issues, and challenges to solve with the data. But somehow going through this we created a system that is working well now," Swaroop said.

It was a lengthy process. Development of the system first started in 2015 with the Dreamweaver team, which had previously worked in the pharmaceutical segment, looking into the supply chain challenges facing the supplement industry. "When we started, we were taken aback by what

was happening when it came to the approach of sourcing ingredients," said Trinanjan Gupta, founder and CEO of TagOne LLC (oral communication, February 21, 2019). "We estimated the lack of transparency at between 90% and 95% for ingredients coming from outside of the United States." Although some outlier companies know their farms and know where their raw material is coming from, the majority of companies do not, he said.

The TagOne team identified several key challenges for the supplement space: lack of visibility of source ingredients due to the global nature of sourcing; concern about the quality of raw materials due to ever-increasing demand but finite supply sources; increasing regulatory requirements; growing consumer awareness of product quality and health effects; and identifying a problem source quickly in the case of a recall or an adverse event.¹³

The TagOne platform covers all transactions in the supply chain including crop management, sales, purchasing, receiving, processing, shipping, and manufacturing across different partner roles (e.g., farmer, trader, proces-

PhytaZenica Startup to Use Blockchain Technology to Accelerate FDA Approval of Botanical Drugs

PhytaZenica is a health care technology startup company that intends to introduce a system using blockchain that will allow for global decentralized digital fundraising for the development of FDA-approved botanical drugs. The blockchain technology will be used to provide a platform for individual investors worldwide to support botanical medicines and quickly raise capital for clinical trials, FDA approval, and commercialization.

Many companies are producing botanical therapies that are more effective, safer, and less expensive than prescription drugs, but they are not getting the traction they deserve in the marketplace because of a system that is biased toward FDA-approved single-chemical prescription medications, according to Jennifer Wong, CEO of PhytaZenica (oral communication, April 12, 2019). "FDA approval is the standard," she said. "That is the culture of our system." Most physicians will not prescribe a therapeutic product that is not approved by the FDA. While use of integrative practitioners is gaining popularity, it is still relatively rare, she said. PhytaZenica's platform intends to offer consumers a form of socially responsible medicine and help provide funding for the medicines that consumers want to see introduced in the market.


Even in China, Wong said, where traditional Chinese medicine (TCM) is the medicine of the people, funding for these therapies is still a challenge. "In Chinese hospitals,

doctors are still trained in Western conventional medicine, so despite the fact that the government is trying to set up equal status for TCM with clinical trials and licensing, doctors are still reluctant to prescribe an unapproved product. Even big TCM companies are coming to the United States to conduct their clinical trials."

The PhytaZenica team saw an opportunity to create a platform that will provide funding and resources for these botanical therapies. The PhytaZenica model includes a blockchain fundraising platform on which botanical companies can raise capital from individual investors around the world.¹⁴ The company is developing a native digital currency called "phyta" to run the blockchain platform and an internal exchange for convenient trading and adoption of the ecosystem's tokens. The company will also provide assistance from FDA botanical drug experts in designing regulatory and clinical trial strategies.

As a secondary step, the company will develop decentralized apps to support botanical therapies and drugs, such as supply chain validation, Wong said.

Although the costs of developing an FDA-approved drug are disputed, current research estimates that a large pharmaceutical company might invest billions of dollars to develop a conventional drug,¹⁵ and it may take as long as 10 to 15 years to complete the process.¹⁶ Given that most botanical product manufacturers are comparatively small,



sor, importer, manufacturer, brand owner, distributor, and retailer).¹⁴ Gupta explained that it was developed around three key pillars: smart phones or tablets for capturing data; the cloud infrastructure to replicate the data; and blockchain technology to ensure that the data cannot be tampered with. “We use a global supply from [many] resources and places around the world that we don’t have easy access to,” Gupta said. “Farmers in China and Africa don’t know where their goods are going. We needed to make it easier for them to fill out the information. In this day and age, we have the technology to do this.”

Engaging farmers and providing practical solutions for them were particular challenges. Having determined that upstream partners like farmers, consolidators, and processors were more likely to use cell phones, the team designed an app that can be used to capture data and is available in English, Hindi, and Mandarin. The TagOne Harvest App offers a simple way for farmers to capture data as the seeds go into the ground and the crops are harvested, said Gupta. Capturing accurate data from farmers efficiently and inexpensively was seen as one of the key problems to solve by the TagOne team and prompted development of the Harvest App.

The app has full traceability and steps to identify plants from seed and field to shelf, according to Trish Flaster, executive director of Botanical Liaisons, who helped create the guidelines for the app. “It has 50 different plants listed with images, sensory evaluation, and information on the farmer, so we know who they are,” she said (oral communication, February 11, 2019). This can help identify issues: if the farmer puts in a longitude or latitude that does not make sense for that particular crop, for example, it would create a virtual red flag. “Knowing the location of the farmer gives the brand or manufacturer an added measure of reliability and trust,” she said.

While supply chain traceability and transparency are the current primary applications for blockchain, there may be other ways the technology can be useful in the botanical products segment. For example, an early-stage startup, PhytaZenica, is developing a blockchain-based platform to raise funding from individual investors for research, development, and regulatory approval of botanical drugs using a digital currency called “phyta” (see sidebar). The company believes that traditional fundraising methods for companies involved with the research and development of botanical drugs (per the US Food and Drug Administration’s

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these costs can be prohibitive, according to Wong. The PhytaZenica solution, she said, provides a more affordable, realistic option, suggesting that the costs of clinical trials to develop botanical drugs are in the range of \$15 million to \$125 million, with a time frame to market that is significantly shorter at less than five years, according to company literature.

Money is raised as investors purchase the phyta currency to fund the initial infrastructure and technology and then investors can also support a particular botanical drug project, receiving tokens tied to that specific project. Drug tokens can be used to purchase approved botanical drugs or be purchased or traded with phyta on the internal exchange. PhytaZenica’s revenue stream will come from commissions for funds raised for botanical projects, token exchange transaction fees, royalties from future botanical drug sales, and strategic investments in promising therapies, among other things.

Botanical drug projects will go through four phases of development in the PhytaZenica ecosystem. The first is a due diligence process to identify botanical therapies with strong market potential that can show either solid clinical trial evidence and/or a track record of consumer use; the second is fundraising for and design of clinical trials to meet the requirements of FDA’s botanical drug approval guidelines¹⁷; the third is FDA approval and commercialization of the product; and the fourth is future royalties and investments.

The company will promote the concept to potential investors through digital marketing and social media. “This is about a grassroots approach and empowering the public to fund their own medicine,” Wong explained. PhytaZenica is currently in the early stages of fundraising for the platform and hoping to raise initial capital with the goal to launch the platform by yearend and the token exchange by early 2020, according to Wong. However, she noted that the blockchain venture environment is evolving very quickly, so a firm timeline is hard to predict.

“We do believe this is a good time to be doing this because of the current political landscape and all the excitement around health care in the 2020 election,” Wong added. “Many people bash ‘big pharma’ for high prescription drug costs. Our aim is to solve the health care crisis from a different angle. The concept of socially responsible medicine will trend well on social media and should resonate for people affected by a broken health care system that is not serving patients or the general public well. This is our way to [solve] the problem.”

In addition, the company believes the platform will contribute to a triple bottom line (People, Planet, and Profit) in that the venture supports the proliferation of botanical drugs, which in general are environmentally friendly, taking less time and money to manufacture and producing less chemical waste. In addition, the company plans to develop a supply chain validation app that may tie into environmental sustainability.

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[FDA's] specific guidelines¹⁵) are time consuming and ineffective and, as a result, many botanical drug products are not getting the FDA approvals and eventual market introduction that they might otherwise warrant. "Supply chain validation is a focus, but not a number-one initial product launch for us because we believe the most urgent need is to drive capital and funding into the [botanical drug] industry," said Jennifer Wong, CEO of PhytaZenica (oral communication, April 12, 2019).

The team ultimately plans to develop apps that will operate on its proprietary blockchain platform. For example, customers, investors, or partners might use phyta tokens to access apps and services connected to the botanical drug supply chain to confirm the origin of botanical ingredients. The system could also be used for the secure sharing of botanical drug clinical data and medical samples with drug developers and FDA to increase the efficiency of the approval process.

Wong believes PhytaZenica's blockchain platform will be cost-competitive because it is highly scalable at 10,000 transactions per second and validates transactions in one second, which takes less computer power and electricity.¹⁵ There are many types of blockchain systems, Wong explained, and some are very wasteful. The PhytaZenica system is a decentralized consortium based on a proprietary software and licensing system. "Many companies are using 'old school' blockchain technology that is very slow and not scalable, with transactions taking about six minutes to validate," she explained. "It's not very realistic. No one wants to wait six minutes for a transaction to validate. The technology needs to be realistic and easy to use; otherwise people won't use it."

Not Yet Ready for Prime Time

To be sure, the capabilities of technology and availability of smart phones to solve ingredient tracking and supply chain issues have made significant leaps in recent years. Nevertheless, many companies are not yet ready to jump on board with blockchain. Beyond the complicated nature of herbal products and their supply chains, some central issues may need to be addressed before blockchain will see widespread adoption. For one, it is expensive. To give this some perspective, the cost per transaction for Bitcoin ranged between \$75 and \$160 in 2018, largely due to electricity use.^{18,19} This adds up. The electricity it takes for consumers every year to mint cryptocurrencies is roughly equal to the annual electricity usage of entire countries, such as Portugal or Romania.²⁰

"Until blockchain becomes less expensive, it is hard to envision a lower margin industry like food or dietary supplements embracing it," Nowacki said. "I am not saying it won't become less expensive, but until it does, if you are making a \$7.99 bottle of fish oil supplements, you don't want to spend \$1.00 [per bottle] on blockchain to track it."

And it is unclear who would be responsible for the added cost. "That is the \$64,000 question," Nowacki added. "Who is going to pay for that? Are we going to charge consumers an extra dollar for that bottle of fish oil tablets? Is CVS going to pay a dollar extra? Is the brand owner or manufacturer going to pay a dollar extra? It's a big problem and a reason that blockchain is currently being held back in the dietary supplement industry."

Another primary concern is interoperability of these systems — in other words, their ability to communicate with one another. Although it is still very early in the space, some blockchain systems already are being developed and used for supply chains in the food industry, including produce, seafood, tea, and dietary supplements. "The technology is in very early days, and we already have a Tower of Babel being built," Nowacki said. "Think about this being rolled out across thousands of ingredients. Suppliers along the way are saying 'Are you telling me I have to submit data to hundreds or thousands of separate proprietary supply chains?'" The longer-term solution is interoperability in which these platforms could talk to each other. "But no one has figured that out yet," he said.

Keeping information private and protecting intellectual property (IP) are also significant concerns. When Gupta started speaking with companies to develop the TagOne platform, he was asked a lot of questions about privacy and IP. The first thing to understand, he explained, is that there are both public and private blockchains. The kind of blockchain seen for Bitcoin is public. Everyone using it can access all the data. The TagOne blockchain is private, so only partners and the TagOne administrators have access to the data. Participating companies also do not have to share details like formulas or sales prices, Gupta noted. "You share ingredient lot numbers only as they move from one point to another. So you have to think only of that product movement and what needs to be tracked," Gupta said.

"If you are ordering a plant from someone, there is no IP involved in that," added Flaster. "When you start adding preparations, then yes, [IP] might be an issue, but that is not necessarily a part of the existing questions. This is just about quality issues."

The Devil Is in the Details

There is also a very common concern about protecting confidentiality of original suppliers to keep companies from skipping intermediary players in the supply chain. Nowacki noted common requests from companies who have asked if there was a way to remove or redact names of original suppliers to protect these sources.

Swaroop noted that one of the biggest obstacles Cepharm faced in implementing the TagOne blockchain system was a similar objection from sales and marketing. “When they learned that we were opening our books to farmers and gatherers, they were worried that we might lose orders,” said Swaroop. He dismissed these issues, believing that there are both challenges and opportunities to complete supply chain transparency. With transparency, he said, “buyers will trust us more, and that will drive loyalty and more orders. Some will go direct or go around us, but they will do that anyway, and this gives us the time and opportunity to weed out the bad suppliers and add good suppliers and create long-term relationships with them.” At the same time, he added, “we are getting complete data from farmers, intermediaries, processors, and suppliers in factories where there are huge issues.”

Greg Sommerville, founder of the Global Supplier Verification consultancy, is inclined to agree that the advantages of transparency outweigh the disadvantages. “I think if each supplier-customer relationship gives value, whatever it is, in whatever part of the supply chain they are in, whether they are on the ground in those countries or keeping certificates, this is not a problem. But you need to provide value to the customer; otherwise they will go around you,” he said (oral communication, March 14, 2019).

Nuherbs’ Lau suggests these issues can largely be solved in the design of a blockchain system. “Do the parties involved become anonymized? What information is part of the blockchain? Who has access to it? There are a lot of issues to consider, discuss, and finalize before it can be widely used. I think the first uses of blockchain will be simple tracking of information, maybe from the last two legs of the supply chain. Or between the brand and the retailer, and the blockchain will contain what the retailer needs to know from the brand,” he said.

Blockchain is an amazing tool that can change the world, said Gupta, but widespread adoption will take time. “We believe in blockchain and stand by it, but it is pretty far down the road. For many companies, they need to go from step one to step eight first,” he said.

Nowacki agrees that many important programs should come before incorporating blockchain into the supply chain, including compliance with regulatory requirements of the Dietary Supplement Health and Education Act of 1994 (DSHEA),²¹ the Food Safety Modernization Act²² (FSMA), and FSMA’s Preventive Controls Qualified Individual training programs, as well as the Foreign Supplier Verification Program.²³ “We deal with customers who don’t even have accurate lists of their suppliers and ingredients, who need basic data cleansing and data collection,” Nowacki said. “Once that’s done, there is the whole lengthy process of gathering all of the basic documents, whether it’s an organic certificate or a third-party audit. And then, once that’s done, there is the whole process mandate by FDA and the Food Safety Modernization Act, assessing all of your suppliers and all of those ingredients. We’ve got to build an entire house, and there are a thousand tasks that go into that. At the end of the process, maybe blockchain is the curtains in the window. But we’ve got to build the house first.”

Newmark, however, points out that blockchain does not have to be an all-or-nothing proposition. “Blockchain is a series of notes on a distributed ledger. It can be used as a one-to-one opportunity without implementing it in the rest of the supply chain. You don’t have to be on it or not. You could start the entire process with one farm on blockchain.”

Another key aspect of moving to the next level with blockchain is quantifying the return on investment (ROI). Swaroop acknowledges that at this point it is difficult to quantify the effect of the technology on Cepharm’s sales. “We opened the data in 2017, and at the time we are seeing more repeat orders, but not necessarily an uptick in sales,” he said.

A Level Playing Field

Swaroop believes the technology is helping to fight some longstanding business issues, such as competing against companies selling an ingredient for a price significantly lower than its market value. “I often can’t figure out how it is possible. We know the farmer and processor but we find another company selling at 20 percent lower than our price.”

This is where knowledge from blockchain could be valuable in providing checks and balances on the production and availability of a specific ingredient. If so much turmeric (*Curcuma longa*, Zingiberaceae) is being harvested, it should correspond with the amount of turmeric root available. If not, the question becomes “Where is it coming from?”

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“I believe we can solve adulteration by using blockchain because if you can see the production of turmeric root is at 7,000 tons [for example] and there was 700 tons of turmeric available, we can check against that,” Swaroop said. “This will level the playing field and translate to a similar cost. So, unless you have some extreme technical innovation in a novel factory, for example, most ingredients products will be available for a similar price.”

This type of transparency may also promote greater trust and efficacy in the market, which is good business. “If I provide transparency, the customer will be more confident and happy to work with me than the guy next door who is playing the discounting game,” added Swaroop.

“Supplement customers are not always looking for the cheapest products but one they can trust,” Gupta said. “I am not saying that if you have a \$4 product you can sell it for \$40, but if you gain customer trust you might be able to sell it for \$8, and that makes good business sense.”

A little bit of upfront cost may be worthwhile, said Flaster, suggesting that knowledge of where ingredients come from can also help to reduce the risk of ingredient or product recalls and the cost of the resulting bad publicity.

Blockchain may also add value from a marketing and valuation standpoint because it effectively reduces risk and exposure. “There is a carrot and stick approach for ROI calculation,” said Trust Transparency Consulting’s Monheit. “Lower exposure is an added element that will become more and more important. Companies that have a transparency-based platform require less due diligence and therefore, in theory, can earn a higher valuation. So, a brand is worth more when it has less regulatory risk.”

Ultimately, once all these concerns and challenges about blockchain are addressed, the last question may be what the industry does when it has achieved widespread blockchain usage. The UK paper acknowledges that it is not yet possible to say whether blockchain systems will actually lead to more sustainable and equitable supply of high-quality botanicals, although it notes that botanical value chains provide a key opportunity to explore this potential.¹⁰ The report concludes that while blockchain may not prevent all the problems, it will increase traceability and make it easier to resolve problems.

Nowacki agrees that the technology has plenty to offer, but it does not account for human error or intentional fraud. “If you strip away all the issues, challenges, and costs, the core benefit is veracity of the data. Nobody can get in and commit fraud. That is a good thing and everybody wants that. Nobody wants a fraudulent ingredient upstream in the supply chain, so it is a good goal,” he said. “At the end

of the day, it is not just about the technology, but humans and the degree to which you can trust them at every step along the way.”

Trust and verification will always be a part of the mix in the herbal supply chain. “No technology, blockchain or otherwise, is going to be a perfect silver bullet against human fraudulence,” Nowacki said. “How do you trust but verify? Good brand owners rely on onsite audits, third-party audits, and laboratory testing for things like pesticides. So we have a system of checks and balances.”

Meanwhile, a few more companies may have to take a leap of faith to prompt broader usage. “We would like to see [blockchain] take a role in the herb industry, but haven’t had overtures from suppliers to my knowledge, and we are reliant on their leadership in terms of supply chain technology,” said Couch.

“Nuherbs won’t implement [blockchain] until there is a generally accepted standard, ease of implementation, and manageable cost of doing so.... The learning curve is steep, so will be the adaptation curve,” Lau said.

Nowacki believes it will take a consortium of technology leaders to come together and work on interoperability to lead to blockchain adoption, but that may take a while. “In my experience, when it comes to setting industry standards and revising technology, that happens not in months but in years,” he said. “I think we are a number of years away from these fundamental problems being solved, so this is not something to budget for in 2020.” HG

References

1. Trust Transparency Center. Single Ingredient Trade Associations Consumer Survey. May 2018. Available at: <https://trusttransparency.com/new-survey-finds-consumers-skeptical-of-synthetic-dietary-supplements-favor-labeling-on-all-synthetic-vitamins-and-supplements/>. Accessed April 9, 2019.
2. ABC-AHP-NCNPR Botanical Adulterants Prevention Program. Available at <http://cms.herbalgram.org/BAP/index.html>. Accessed March 19, 2019.
3. Raterman K. AHPA’s Self-Regulatory Initiatives in the US Herb Industry. *HerbalGram*. 2018;118:50-53. Available at: <http://cms.herbalgram.org/herbalgram/issue118/hg118-legreg-ahpa.html>. Accessed July 25, 2019.
4. AHPA Botanical Authentication Program. AHPA website. Available at: www.ahpa.org/Resources/TechnicalGuidance/ScientificAffairs/BotanicalAuthenticationProgram.aspx. Accessed March 19, 2017.
5. ABC Staff. American Botanical Council Celebrates 30th Anniversary. *HerbalGram*. 2018;120:13-15. Available at: <http://cms.herbalgram.org/herbalgram/issue120/hg120-abcnews-30thanniv.html>. Accessed July 25, 2019.

Ultimately, once all these concerns and challenges about blockchain are addressed, the last question may be what the industry does when it has achieved widespread blockchain usage.

6. Supplement Safety and Compliance Initiative website. Available at: www.ssciglobal.org/. Accessed March 19, 2019.
7. Goyal S. The history of blockchain technology: Must know timeline. 101 Blockchains. Nov. 3, 2018. Available at: <https://101blockchains.com/history-of-blockchain-timeline/> Accessed March 18, 2019.
8. Kucirkova A. How blockchain is improving the global supply chain. IQSDirectory. Available at: www.iqsdirectory.com/resources/how-blockchain-is-improving-the-global-supply-chain/ Accessed March 18, 2019.
9. Walmart Food Traceability Initiative. Walmart website. Available at: https://corporate.walmart.com/media-library/document/blockchain-supplier-letter-september-2018/_proxyDocument?id=00000166-088d-dc77-a7ff-4dff689f0001. Accessed March 28, 2019.
10. Heinrich M, Scotti F, Booker A, Fitzgerald M, Kum KY, Lobel K. Unblocking high-value botanical value chains: Is there a role for blockchain systems? *Front Pharmacol*. April 2019. Available at: <https://doi.org/10.3389/fphar.2019.00396>. Accessed June 28, 2019.
11. Lee J. Is Mass Balance Pushing Your Chocolate Bar Too Far? Triple Pundit. April 28, 2015. Available at: www.triplepundit.com/story/2015/mass-balance-pushing-your-chocolate-bar-too-far/35231. Accessed July 25, 2019.
12. Guidance for Working with the Rainforest Alliance Mass Balance Sourcing Program. Rainforest Alliance website. Available at: www.rainforest-alliance.org/business/wp-content/uploads/2018/10/mass_balance_guidance_EN.pdf. Accessed April 9, 2019.
13. TagOne Origins. The need for comprehensive traceability. TagOne website. Available at: www.tagone.com/solution-background Accessed March 19, 2019.
14. TagOne Functionality. Focus on usability. TagOne website. Available at: www.tagone.com/focus-on-usability. Accessed March 19, 2019.
15. DiMasi JA, Grabowski HG, Hansen RW. Innovation in the pharmaceutical industry: New estimates of R&D costs. *Journal of Health Economics*. May 2016;47;20-33. Available at: www.sciencedirect.com/science/article/abs/pii/S0167629616000291. Accessed April 14, 2019.
16. Wong J. PhytaZenica White Paper: Accelerating FDA Approval of Botanical Drugs to Improve Global healthcare and Drive Explosive Growth in the Drug Industry. PhytaZenica. Version 1.3. March 22, 2019.
17. Botanical Drug Development Guidance for Industry. US Food and Drug Administration website. Available at: www.fda.gov/downloads/Drugs/Guidances/UCM458484.pdf. Accessed April 14, 2019.
18. Bloomberg, J. Don't let blockchain cost savings hype fool you. *Forbes*. February 24, 2018. <http://www.forbes.com/sites/jasonbloomberg/2018/02/24/dont-let-blockchain-cost-savings-hype-fool-you/>. Accessed March 21, 2019.
19. Blockchain Luxembourg. Blockchain cost per transaction. Available at: www.blockchain.com/charts/cost-per-transaction. Accessed March 21, 2019.
20. Bitcoin energy consumption index. Digiconomist website. Available at: <https://digiconomist.net/bitcoin-energy-consumption>. Accessed March 21, 2019.
21. Dietary Supplement Health and Education Act of 1994. National Institutes of Health Office of Dietary Supplements. Available at: https://ods.od.nih.gov/About/DSHEA_Wording.aspx. Accessed March 22, 2019.
22. Food Safety Modernization Act (FSMA). FSMA Rules and Guidance for Industry. United States Food and Drug Administration. Available at: www.fda.gov/food/guidance-regulation/fsma/ucm253380.htm. Accessed March 22, 2019.
23. Foreign Supplier Verification Programs for Importers of Food for Humans and Animals. United States Food and Drug Administration. Available at: www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM593079.pdf. Accessed March 22, 2019.

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