



TRUTAG TECHNOLOGIES:

Digital Health Meets the Internet of Things

KEY POINTS

- TruTag Technologies has developed an ingestible tagging system that can be inexpensively incorporated into pharmaceuticals, medical devices, and other products. The company's microtags are able to carry billions of spectral codes, equating to enormous amounts of information, which can be read with an optical reader.
- Packaging can be counterfeited, but TruTag's microtags are integral parts of products and can be interrogated at every step of the supply chain, from manufacturing to the hands of consumers.
- The company's most developed market is pharmaceuticals, where counterfeiting is a big problem in terms of safety and lost revenues. Medical device companies, especially those with high-value consumables, could also benefit from the product security offered by the microtags. Indeed, device companies are now required to directly tag certain medical devices after a recent ruling by the FDA concerning Unique Device Identifiers.
- While TruTag operates in a category known as PIATS (product identification, authentication, and tracking systems) its vision is much broader. In the future, consumers might use smart phones to "read" products, giving manufacturers an opportunity to establish a dialogue with end-users.

by
MARY STUART



Information technologies are changing every aspect of material products; how they're manufactured, how they move through the supply chain, and how customers interact with them. Technological advances in all three areas include additive manufacturing, otherwise known as 3D printing; RFID tags and readers to smooth out the supply chain logistics; and smart phone apps in the hands of consumers. Indeed, smart phones have become small computers and readers that enable what David Rose of the Massachusetts Institute of Technology calls "the enchantment of everyday objects" (in his book *Enchanted Objects: Design, Human Desire, and the Internet of Things*).

The "internet of things" is the notion that technology enables value-enhancing information to reside inside the objects we use every day—pill bottles, pens, or toothbrushes, for example, and not just in intermediary technologies like smart phones and tablets—to increase safety, encourage compliance, enhance a consumer's experience, and bring market intelligence back to manufacturers. (The digital insulin pen of **Emperra GmbH E-Health Technologies**, [profiled in this issue of *The MedTech Strategist*](#), is a good example.)

TruTag Technologies Inc. has a novel technology platform for fulfilling all of those goals and more. Operating at the intersection of materials science and information technology, TruTag believes it is in a position to provide value for every aspect of engagement with a product, from manufacturing to the customer's experience.

TruTag has invented and patented a unique tag that is embedded into products during their manufacture. The size of a dust particle, the *TruTag* microtag is edible, can withstand harsh manufacturing condi-

tions (a temperature of up to 1600 degrees centigrade, for example), carries enormous amounts of information (e.g., about a product's lot number, the provenance of its materials, where it was manufactured, and billions of other bits of useful data), is inexpensive to manufacture, and has an "indefinite" shelf life.

The company's microtags are applicable to many industries where manufacturers are concerned about counterfeiting and/or safety—electronic products, industrial components, consumer goods (especially high-end consumer brands such as top-shelf wine or designer apparel), food, drugs, and medical devices. The list is endless, and that is one of the company's major challenges: how to execute product strategies across so many potential verticals.

Hank Wuh, MD, founder and CEO of Skai Ventures LLC, which founded TruTag, says the company has a sharp focus on high-value, high-volume products where its platform can solve specific problems for manufacturers. With an ingestible product, TruTag is particularly well-positioned to authenticate food, medical devices, and drugs, and indeed, its strategy is most developed in the pharmaceutical industry, a \$5 billion market opportunity that is only the company's first target.

Purposeful Incubation

TruTag was spun-out of the venture capital firm/accelerator Skai Ventures in 2011. Skai founder Hank Wuh is an orthopedic surgeon who was trained at Harvard University, the Johns Hopkins School of Medicine, and Stanford, so it's not surprising that the bulk of its investments to date are in healthcare-related fields. Skai has been focused on two major areas of innovation—health services, with several centers focused on ambulatory surgeries and urgent care, and novel materials, a category that includes two of its portfolio companies: TruTag Technologies, and **Eyegenix LLC**, which is developing a biosynthetic cornea for the treatment of corneal blindness.

Says Wuh, "We had an idea about the use of a completely inert material that could be manufactured very efficiently, that would be ingestible, made from an FDA-approved excipient, and could contain billions of combinations of spectral data for tracking anything that needs to go into the human body." Wuh recruited as chief scientific officer Michael O'Neill, PhD, a biophysicist with a background in both optical data storage and IT security, and incubated the concept for five years. "Over that period of time, we proved that indeed we could make such a taggant, encrypt it, read it, and manufacture it on a very large scale."

Protecting pharmaceutical companies against counterfeiting is the company's first application. TruTag has developed what is essentially an invisible barcode; a dust-sized

chip made of silica (which presents no safety issues since it is already an approved excipient used in drug coatings), into which billions of spectral codes can be embedded. The codes will one day be read by smart phones, but the company recently introduced a standalone reader, the *Model 4100*. This device is a high-performance optical reader that connects to the cloud and incorporates what the company calls a "first-of-its-kind" solid state imaging and processing engine (see *Figure 1*).

Figure 1
TruTag's
Model 4100
Optical Reader



Source: TruTag Technologies Inc.

As noted, the *TruTags* are ingestible (see *Figure 2*), which makes them safe inside the human body, but they require line-of-sight to be read. They aren't designed to be readable from within the body, as are the pills of **Proteus Digital Health**, which operates in a different sector of the pharmaceutical industry, with sensor-enabled pills designed to track adherence, sleep patterns, and activity levels after swallowing. TruTag microtags are interrogated by an external reader and hence provide no potential concerns regarding intrusion into patient privacy.

Much information can be encoded onto a *TruTag*. "Over one billion spectral codes are achievable—the brand name, lot code, manufacturing site, even the entire drug package insert, in every known human language could be accessed from the surface of the pill," says Wuh. For all that functionality, the microtags can be manufactured without a meaningful impact to the product's cost of goods.

A Tiny Tag Solves Enormous Problems

Drug counterfeiting is "not a victimless crime," says Wuh. There are obvious safety risks. "No one wants to take a fake drug," he points out. But of course counterfeiting is also a source of revenue loss. Counterfeit drugs account for \$200-\$400 billion in lost revenues per year. "And this is just the cost of counterfeiting and diversion in the pharmaceutical industry. We're not even talking yet about food safety, the

traceability of organic food, or medical devices.” The pharmaceutical industry manufactures 1.5 trillion pills each year, and about a third of them are high-value, branded, and a target for diversion, parallel import, and issues with tracking and tracing, says Wuh. That is the company’s initial market.

Beyond counterfeiting, it’s important for manufacturers to be able to track and trace products for a number of reasons. Parallel importing is another source of lost revenues for pharma companies; that is, the same drug is often sold at different prices for different markets, and various entities will try to buy the drugs in the lowest price markets and sell them for the highest price. One such example is *Sovaldi*, the high-priced hepatitis C drug manufactured by **Gilead Sciences**, which has a diversion problem in the billions of dollars. “Pharmaceutical companies can’t track all these drugs intended for different parts of the world, but we can. A batch that is supposed to go to a certain region can be uniquely coded so that the security team for the pharma company, the pharmacy, the customs patrol, or the hospital can readily identify that the drug is being used in its intended market.”

Finally, tagging can help patients and caregivers. Wuh says, “My mother was in the hospital a few years ago. A

nurse brought her six pills in a cup. Those pills went from the doctor’s order to the pharmacist, to the nurse, to the orderly, then to the person who brought the pills to the room.” That leaves plenty of room for error, he notes. “You want to know that these are six of the right pills. With our system, you take the reader and within a few seconds you could see who made the pill, where it was made, when it expires, and you might even see a database that details drug-to-drug interactions. It is a fool-proof system that is extremely powerful.”

The company and its customers have only just begun to envisage the applications for this technology. “Let your imagination run wild for a minute, says Wuh. “If we can track the movement of every single pill through every stage of the supply chain from the manufacturer to the patient, imagine what we could do.”

As noted, the company’s business development is most advanced in the pharmaceutical industry. The firm says it is working with several multinational pharmaceutical companies on pilot testing for broad deployment of its technology on solid oral dosage form products. In 2014, TruTag entered into an agreement with the Chinese CRO and contract manufacturing company **WuXi PharmaTech Inc.** to explore collaborations with WuXi’s global customers on the incorporation of the TruTag system into their solid drugs. As part of the agreement, the corporate venture arm of WuXi made an investment in TruTag.

In August 2015, TruTag hired an experienced business development executive for the pharmaceutical markets. Steven Yoder spent 30 years in pharmaceutical manufacturing technologies, including formulated film coating systems, modified release technologies, and functional excipients, or, as the press release announcing his appointment notes, “experience in selling multiple brand enhancement products and services.”

TruTags for Medical Devices

TruTag technology is safe for implantation in the body, and Kent Mansfield, president of TruTag, notes that there are obvious applications for medical devices. Mansfield joined the company in 2011 and brings a background in product security or brand protection through products that help avoid compromise and counterfeiting, as he describes it. Mansfield has worked with product labeling systems in the past and says that three things struck him as unique about the *TruTag* microtag. “It is edible, it is a well-known material that has been studied and included in food and drugs for decades. It withstands heat—up to 1600 degrees, and that opens up industries that otherwise wouldn’t be available, like plastics and integrated circuits.”

Another unique competitive advantage is the company’s ability to variably code tags. Inorganic taggants aren’t new,

Figure 2

TruTag Microtags Are Ingestible



TruTag microparticles are uniquely etched through a highly proprietary process and associated with an specific optical signature without the use of additional additives or markers. The high-purity silica tags can thus be added to coatings and cores and be applied to the exterior of edible goods, or added to ingredients such as powders and used as a forensic marker, to be read and verified as part of an investigation or inspection process by authorized security or quality assurance personnel.

Source: TruTag Technologies Inc.

he says, but earlier labels were engineered, took time to manufacture, and resulted in only one signature. “It would allow you to authenticate, but not much more.” In contrast, TruTag can make thousands of taggants for a single company to go on all of their products and all of their dosage forms. “It really allows a granular capability to identify products at their source. Where were they made? What equipment line where they made on? It opens the door for a granular identification of the product origin, which has never before been possible.”

TruTag is coming to market at a time when it can serve the device industry’s need for Unique Device Identifiers (UDIs) directly on certain products, under a recent ruling from the FDA. The new ruling requires manufacturers to detail serial numbers, lot numbers, expiration dates, manufacturing date, and other information that will hopefully lead to more accurate reporting of adverse events, help identify quality control issues, and facilitate recalls—problems that are unique to the medical device industry.

Mansfield notes that to a certain extent, medical devices are also subject to counterfeiting, especially with respect to consumables. “There are sensors for glucose monitors, injectable delivery devices, and other consumables that are unique and patented and the source of a company’s revenue stream.” Mansfield says there is a lot of criminal interest in faking consumables and selling them into the market at a high price. “But most often they are cheaply made and don’t meet specifications.” Again, these spurious medical products present safety as well as financial risks. “One of the big problems companies have these days is that they are unable to track the source of their supply once it is out in the marketplace. The product tends to get repackaged by distributors, and you can no longer rely on the packaging because so much product is fake now.” Mansfield says “We offer a way to go directly to the product itself, interrogate it, and audit its authenticity and its origin.”

For Medical Device Companies, Access to the Consumer

TruTag currently operates in the category known as PI-ATs (product identification authentication and tracking systems) but Wuh’s plans are much broader. “Our vision is that someday this tag will be on most major brands in the world. The consumer might use our smart phone reader to authenticate the product, or to learn something they want to know about it. Where was it manufactured? What is its carbon foot print?” At that point, however, he imagines that the manufacturer could also take the opportunity to establish a dialogue with the customer. When the consumer interrogates the product, the manufacturer could ask them, “Would you prefer this if it were peach instead of strawberry? Do you buy this product once a week

or once a month? Would you like to have a 10% off discount coupon? What can we do to improve our products and your experience?”

Many medical device companies acknowledge their inability to directly reach end-users, who are patients, and sometimes physicians. It’s one reason why they’ve embarked on social media strategies. (See “*Medtech and Social Media: Building a Strategy around Likes and Tweets*,” The MedTech Strategist, October 16, 2015.) Embedding information directly into the product might be a way to reach patients, to influence their adherence and compliances, and to understand their preferences. Again, this gets close to the vision of the “internet of things,” where everyday products are embodied with intelligence about the particular customers they serve.

“Our vision is that someday this tag will be on most major brands in the world. The consumer might use our smart phone reader to authenticate the product, or to learn something they want to know about it.”

—Hank Wuh

Wuh notes that the company has a pharmaceutical reader deployed in the field, and is “on the launchpad” for creating a smart phone-enabled reader that will allow consumers and people in the field to interrogate products,” in an 18-24 month time frame.

The opportunities are countless. TruTag truly has a technology in search of applications, and while in the world of pure medical device start-ups that usually isn’t a good thing, the world of IT is different. Market expansion occurs in the hands of users who push technologies into new areas. When cell phones first came out with cameras, who thought that we needed them? Teenagers, that’s who, sharing spontaneous snaps with their friends. But now, cameras enable smart phones to offer serious medical applications; phones can be microscopes for skin diagnostics, portable ultrasound devices, and scanners and readers of all kinds of data. The applications and markets for TruTag will expand the same way, by users who understand their own needs in light of the new tools. The company has established leaders in each of the verticals it is targeting to help address specific needs. Wuh says, “For your pharma and medical device readers, if there is any interest in the ability to track, trace, improve supply chain logistics, improve the ability to mitigate very quickly in the event of recalls, and establish that level of communication with the physicians and end-users, please contact us.” 