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FIGHTING FAKE DRUGS

TAGGING TECHNOLOGIES may help deter counterfeiting of medicines

LEONORA WALET, CONTRIBUTING EDITOR

SAFETY LEGISLATION in major pharmaceutical markets is fueling demand for efficient ways to track and trace drugs along the distribution chain. Tagging technologies could offer solutions, if barriers to implementation can be overcome.

The U.S. recently enacted rules to thwart counterfeit drugs. The 2012 FDA Safety & Innovation Act gives the Food & Drug Administration extra powers to monitor drugs imported into the country. And the 2013 Drug Quality & Security Act requires the creation of an electronic system to identify and trace certain drugs as they are distributed. Manufacturers, wholesalers, repackagers, and pharmacies will be called upon to cooperate with FDA to develop the system in the next 10 years.

The same commitment is mirrored in Asia. In 2013, China's State Food & Drug Administration implemented new rules requiring companies to use bar codes, electronic monitoring, and standardized documentation to trace drugs through the supply chain. In April 2014, India's Directorate General of Foreign Trade told pharmaceutical exporters to adopt a track-and-trace system for their products.

"The fight against counterfeiters is a huge business," says Moses Akintomide-Akinwamide, senior analyst at Visiongain, an information provider for the pharmaceutical and other industries. "Asia is increasingly a growth area," he explains, because a major portion of fake drugs comes from China and India. At the same time, reputable drug companies in those countries "are hungry for success," Akintomide-Akinwamide says. "Part of achieving success is protecting their brands from counterfeits."

FINGERPRINT A vial holds TruTag's silicon dioxide taggants.

In the battle against counterfeit medicines, new weapons in the works are too small to be seen with the naked eye. They are micrometer-size particles, or microtags, containing information to identify and track drugs along the supply chain. Microtags are uniquely encoded with multiple levels of security information within a space of 50–110 μm—the size of a dust speck and thinner than a strand of human hair.

The tags are usually made of materials that FDA regards as inactive ingredients, which means they are considered safe to eat and don't alter the integrity and potency of a drug. The encoded information can be decoded with laser pens, optical scanners, or other scanning technology provided by the microtag maker.

COUNTERING COUNTERFEITS BY THE NUMBERS

$75 billion
Value of fake drugs sold in 2010

$1 trillion
Annual value diverted from global economy by counterfeit products

$100 million
Size of taggant market

12 million
Number of individual tags in 1 g of microtag particles

50–100 μm
Diameter of a typical microtag

Global sales of fake drugs reached $75 billion in 2010, according to the U.S. Center for Medicine in the Public Interest. More broadly, counterfeit products divert $1 trillion annually from the global economy, warns the International Chamber of Commerce. Doubling down on authentication methods is one way to fight this threat.


TRUTAG

For technology developers, the potential is big. According to Visiongain, the global market for pharmaceutical anticounterfeiting technologies has reached $1 billion per year and is growing fast. Tagging technologies—including microtags, biological taggants, and optical markers—account for more than $100 million of this figure and could reach $250 million in a few years, Akintomide-Akinwamide says.

With an eye on this growing market, Honolulu-based TruTag Technologies has introduced microtags made of silicon dioxide, an additive commonly used in food processing. The tags, which can be incorporated in solid drug formulations, become the unique identifiers of each batch of pills, similar to a fingerprint.

THE TAGS ORIGINATE from a silicon wafer electrochemically etched with a pattern that corresponds to a unique spectroscopic signature, explains TruTag President Kent Mansfield. When the wafer is ground into powder, each particle contains the signature. A gram of TruTag particles contains more than 12 million tags, Mansfield says, each tag bearing information such as the product, dosage type, and lot or batch number.

The yet-to-be-commercialized technology has caught the eye of WuXi PharmaTech, a Chinese pharmaceutical services company. WuXi has invested in TruTag and is aiming to integrate the approach into its drug manufacturing processes. "We're conducting experiments to prove that this technology will not have an impact in the pharmaceutical production process," says Edward Hu, WuXi's chief investment and chief financial officer. "If this technology works well, we'll offer it to our clients."

Meanwhile in New York, Stony Brook-based biotechnology firm Applied DNA Sciences has developed a tag that uses plant-based DNA. The double-stranded DNA strand is broken into segments that are then shuffled and reassembled to form an encrypted, unique DNA marker. After it has been encapsulated to make it durable, the DNA marker is embedded into product packaging or made part of a pill coating.

Counterfeiters will find it difficult to circumvent microtags, Akintomide-Akinwamide says, because they can't be detected and read unless amplified or replicated billions of times, an expensive proposition. Even if counterfeiters could somehow copy a code, it would be hard for them to keep pace. As TruTag's Mansfield explains, the company can generate thousands of codes easily: "It's a software change for us."

Still, success is uncertain. NanoInk, which sought to nanoemboss information on pills, filed for bankruptcy in 2013. And as of 2013, ARmark Authentication Technologies was no longer listed as a division of its parent, Adhesives Research. ARmark had proposed to include microtags in films used to coat pills. Adhesives Research did not respond to requests for comment on its reason for discontinuing ARmark.

Microtag suppliers still in the game must demonstrate how well the tiny identifiers can be integrated into pharmaceutical manufacturing without compromising drug composition, safety, and efficacy. Douglas Mendenhall, a pharmaceutical industry veteran who runs his own North Carolina-based consulting firm, believes it is feasible to add microtags as an inert drug ingredient but cautions that getting FDA's nod could be tough.

Uniform distribution in production batches needs to be established, Mendenhall says. And that is not a trivial undertaking. Once blended, the particles could alter the drug's physical performance and properties. Ensuring that detrimental changes do not occur can be a multi-million-dollar job, he cautions.

"Like any new technology, adoption by the industry will take some time," WuXi's Hu acknowledges. "It is extra challenging in the pharmaceutical industry because it is highly regulated."

But if WuXi has the staying power and financial muscle to do the development work, "they'll get it right," Mendenhall predicts. As add-on security, microtags "could be sellable," and they could differentiate WuXi from other drug service companies, he says. "Who knows? It might catch on."

Leonora Walet is a freelance writer based in Hong Kong.

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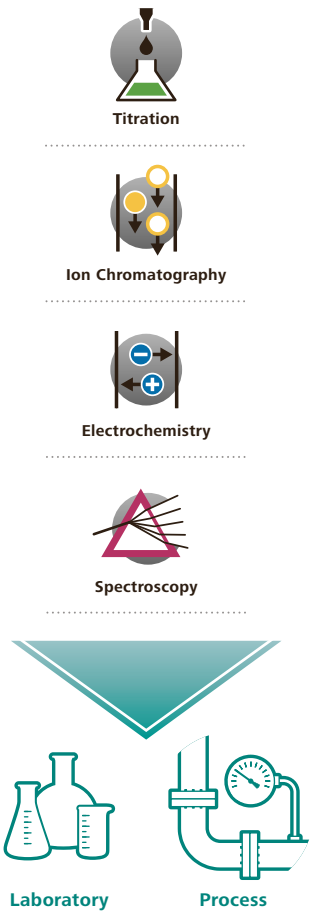

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