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# tablet and capsule marking

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BEYOND AESTHETICS: MARKING TABLETS AND  
CAPSULES TO COMBAT COUNTERFEITING

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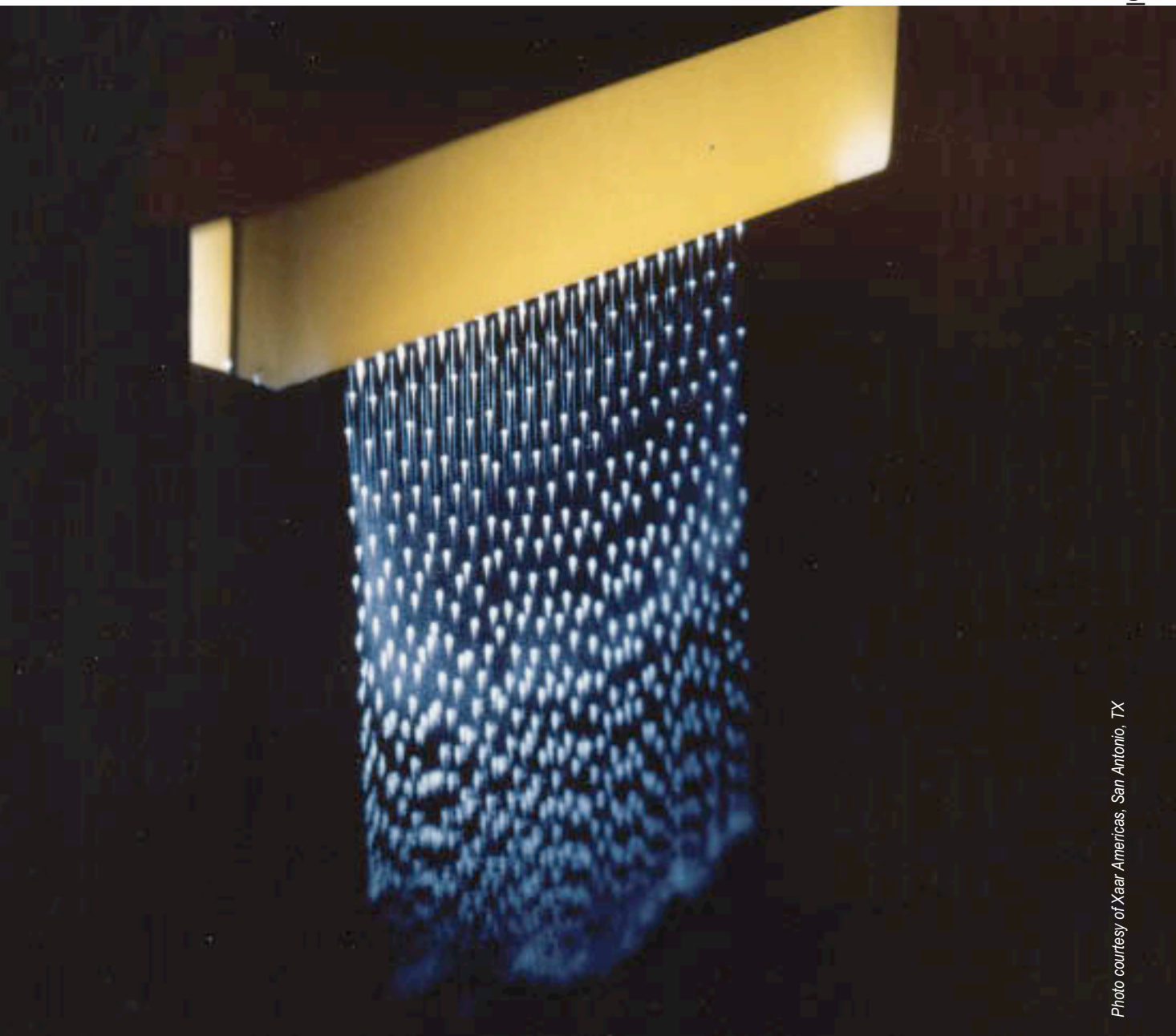


Photo courtesy of Xaar Americas, San Antonio, TX

A decade ago, marking tablets and capsules was often a marketing decision. It enabled manufacturers to be creative in differentiating their products with logos, designs, and product information.

Today, tablet and capsule marking plays an important role in fighting counterfeit drugs, which is a growing threat. According to the World Health Organization (WHO), in 2003 fake medicines accounted for 5 to 8

percent of the global drug supply. Investigators at the FDA say the true number is closer to 10 percent, and it may be as high as 25 percent in developing countries.

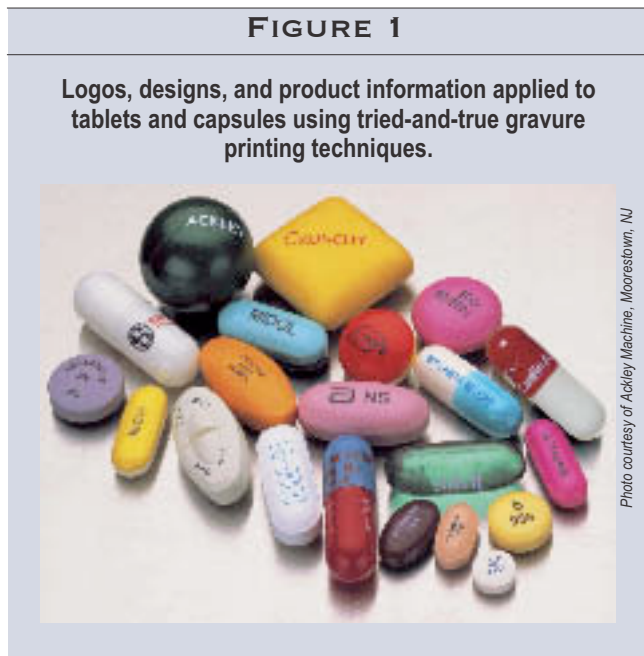
The lure of money is at the center of the problem. Authorities estimate that counterfeiters rake in \$32 billion annually from fake medicines. That's a big blow to the financial well-being of legitimate manufacturers and doesn't account for the damage done to consumers' health and to their confidence in the drug supply. Counterfeiting blockbusters such as Viagra, Lipitor, and Cialis has become so lucrative that some criminal organizations have switched from peddling street drugs to counterfeiting prescription pharmaceuticals. And counterfeiting is not only costly, but deadly. Over the past decade, hundreds of thousands of deaths have been tied to bunk meningitis and malaria treatments alone.

### An integrated approach

The FDA is working with the WHO, Interpol, and other international organizations to combat counterfeiting. Last year, the FDA initiated 58 counterfeit medicine investigations, nearly twice the number conducted in 2003.

Vendors of pharmaceutical equipment and supplies have joined the anti-counterfeit effort. One of the first techniques to gain acceptance, radio frequency identification (RFID) does not apply a marking to tablets and capsules. Instead, it uses radio transmitters affixed to packages, cartons, and pallet-loads to communicate with receivers.

In November 2004, the FDA issued a guidance encouraging the industry to test RFID in feasibility studies and pilot programs. The goal was to increase the safety and security of the nation's drug supply. But applying RFID to small packages—never mind single tablets and capsules—can be impractical. And RFID coding can be cracked, making it vulnerable to tampering. In short, RFID alone is not the final answer to the counterfeiting problem.



“When the FDA issued the report indicating that the industry should do something by 2007 and should consider adopting RFID technology as the answer, we looked at that and said, ‘We don't think, based on our experience, that there's one silver bullet like RFID or e-pedigree,’” said Simon Raban, program manager of life sciences product tracking and authentication at Hewlett-Packard (HP), Palo Alto, CA. “We felt that a combination of technologies, approaches, and business processes was required.”

That's because tracking a product through the supply chain is not the same as authenticating it. “You track the product through the supply chain, and then you apply features that you can use to authenticate it,” Raban said. “We think that this is required at all product levels—from



unit dose through the pallet.”

Dan Prossicki, a senior sales engineer at Videojet Technologies, Wood Dale, IL, agrees. “I think where it is going, in terms of using various types of technologies, is to get to 100 percent traceability down to the individual products themselves.”

### Anti-counterfeit strategies

Applying bar codes is another facet of the strategy. The FDA's final barcode rule, published in February 2004, requires most prescription labels and certain OTC medicine labels to carry a linear bar code that identifies, at minimum, the product's National Drug Code (NDC). The objective is to help health care professionals verify that the right drug is given to the right patient at the right time. But the rule only applies to labels, not the tablets and capsules inside the package.

“We're confident that once the FDA is assured that there's a technology that can achieve consistent marking with the information that will prevent medication errors, it'll be mandated,” said Andrew Jackson, applications marketing manager at Sherwood Technology, Widnes, UK. “I think they're just waiting to verify that the technology

**FIGURE 3**

**A thermal inkjet manifold containing three inkjet cartridges. Thermal inkjet printing is among the faster and cleaner tablet and capsule printing techniques.**



Photo courtesy of Inc.Jet, Norwich, CT

That same technology might also help outmaneuver the counterfeiters. “Right now, the counterfeiters can buy the exact same equipment that the major pharmaceutical companies can buy, so they’re already on equal playing ground,” said Keith Smith, sales manager at Xaar Americas, San Antonio, TX. “If there are ways to manipulate the image that goes down, with subtext and things like that that can’t be done with traditional printing processes, such as gravure, then we’ll be ahead of the counterfeiters.”

In fact, some companies are already using advanced marking techniques. Three popular approaches are reduced space symbology (RSS), two-dimensional (2D) matrix codes, and linear bar codes. Embedding taggants into coatings or even the formulation is another approach being investigated. Taggants are unique identifiers that enable investigators to authenticate tablets and capsules using infrared, ultraviolet, or other types of scanners.

### **Ink think**

Ink-based technologies are at the heart of many anti-counterfeiting measures. Gravure printing and traditional pad-type printing perform well when applying logos and simple graphics to tablets and capsules. And these tried-and-true technologies are still widely used today. See Figure 1. But other approaches are more flexible and may perform better, depending on the application.

“The pad printing technology of today is 50 to 60 years old,” said John Kawochka, senior vice president and chief technology officer at Efficient Automated Machine (EAM), Long Island City, NY. Pad printing is similar to ink stamping, and can smear the logo or lettering and produce images that are too light or too dark. It also requires direct contact with the tablet or capsule, which raises the risk of breakage. What’s more, pad printing systems are not ideal for high-speed production, and they are

One alternative is non-contact inkjet printing, which is available in a variety of configurations, including thermal inkjet printing. See Figure 2. “There are many advantages to thermal inkjet printing over pad-type printing,” said HP’s Raban. It’s cleaner, sharper, faster, cheaper, and easier to set up and maintain, he said. “These inks can be applied very quickly, at very high resolutions, and in variable ways. We’re testing between 300 and 600 dots per inch (dpi). It’s really a matter of speed, real estate, and the type of substrate you’re printing on.”

A possible drawback to thermal inkjet printing is the heat used to discharge the ink from the cartridge. “The underlying principle of ‘bubble jet’ is that it uses the boiling point of water to basically explode the ink or fluid out of the print head,” said Xaar’s Smith. The heat is rarely a problem in most applications, but it may compromise the surface of tablets and capsules and thus jeopardize their performance.

Others see no reason for concern. “The actual temperature of the ink coming out is far below boiling,” said Steve Wood, strategic alliance manager at Inc.Jet, Norwich, CT. Inc.Jet was one of the first companies licensed to use HP’s 45A inkjet cartridge for industrial applications. See Figure 3. “The ink is warm, but it’s extremely well tested so that there’s no risk whatsoever.”

Continuous inkjet printing, like that offered by Videojet, is similar to thermal inkjet printing, only it doesn’t rely on heat to dispense fluid. Instead, it uses an electric field to deflect and control a continuous stream of ink droplets.

“We’ve got about nine or ten different types of food-grade fluids,” said Videojet’s Prosidicki. “We’ll take a customer’s product—whether it be a tablet, capsule, gelcap, whatever—and we’ll actually provide samples with specific inks.” That way, the customer can analyze the ink to ensure it is compatible with the surface of the tablet or capsule.

“You need an ink that’s going to be compatible with your surface,” said Philip Gulotta, sales engineer at Ackley Machine, Moorestown, NJ. “What you want the ink to do is basically become tattooed in there. You want it to become part of that surface.”

Continuous inkjet printing can mark tablets or capsules at a rate of about 900 feet per minute, but there’s a tradeoff for this speed. Continuous inkjet printing is more costly than thermal inkjet printing. And since the ink flows in a continuous stream, any ink not deflected onto the substrate is recirculated. Over time, this alters the ink’s viscosity, so careful monitoring and ongoing calibration are needed.

Piezoelectric inkjet printing, another approach, is offered by Xaar and Epson America, Long Beach, CA. Like thermal inkjet printing, piezoelectric inkjet printing is a drop-on-demand technique, but no heat is required. Instead, a small electric charge vibrates a crystal, forcing ink from the nozzle. “We take a flat piezo crystal material, laser-ablate little tiny channels into it, and then

said Xaar's Smith. "That opens up the gamut of what we can eject out of the print heads." Piezoelectric inkjets can also print in gray scale. "Out of every single nozzle, we have the ability to jet multiple drop sizes—3, 6, 9, or 12 picoliters," Smith said. Surrounding large drops with smaller drops smoothes out the edges of the large drops, enabling Xaar to achieve a perceived 1,600 dpi. The primary drawbacks of piezoelectric inkjet printing are cost and speed.

No matter the approach, every symbol or code must be applied using food-grade inks. The FDA has already approved for pharmaceutical use many ink ingredients, but the ingredients in some covert inks and taggants are still under review.

### In favor of lasers

Lasers have been used for years to drill holes in tablets to produce a pulsatile release of the API. "There are tablets that are bi-layered," said Ackley's Gulotta. "One layer has a hole in it, and that actually acts as a pump inside your stomach to release the medication over a certain period of time."

Today, lasers offer an alternative to inkjet printing. "From a laser standpoint, 10 years ago, marking on tablets and capsules was virtually unknown," said Andrew Knight, a laser technology sales specialist for Videojet. "Now, with vector-scanning lasers, we can approach the speeds that pill manufacturers demand to be met as far as laying down codes." Between 90,000 and 150,000 tablets or capsules an hour is typical.

Using lasers to etch product information or security codes onto tablets removes some of the product's coating. That may be acceptable if the coating is cosmetic, but problematic when it's functional. "If it's an integral part of the way the medicine works, then you definitely have to look at that," Knight said. "But if it's just there for aesthetic reasons, it's typically not a problem."

To avoid that problem, Sherwood uses a technique called DataLase. It applies a color-changing agent to the coating, then chemically activates the agent with a low-intensity laser. Only the areas pinpointed by the laser change color, creating high-resolution imagery without compromising the integrity of the product's surface.

"We're manipulating beams and creating scanning systems to produce images onto substrates," said Sherwood's Jackson. Like inkjet inks, all ingredients are food grade. And the technique creates almost any symbology, from basic alphanumeric codes and linear bar codes to 2D matrix codes and RSS.

Sherwood's latest technology, DigiVU, provides even more protection against counterfeiters. It creates graphics using a proprietary ultraviolet laser, not the commercially available CO<sub>2</sub> laser that DataLase uses. And DigiVU achieves a resolution as high as 2,500 dpi. "You can get a miniature photographic image that is totally

recognizable once magnified," Jackson said. Although impractical, it can even apply patients' photographs onto their medication.

"Virtually anything that can be software-generated could be imaged onto tablets at very high resolutions," Jackson said. "The fact that it's too small to physically see with the human eye is not an issue, because there are machine readers that can scan it, read the data, and verify that it's authentic." In addition, the low-intensity lasers produce little heat and are unlikely to compromise the tablet's surface.

### Making it happen

If there's one common theme among vendors of tablet and capsule marking systems, it's the drive to collaborate. That's because customers want turnkey systems.

Take HP, for example. "We started in the OEM business because we didn't want to go into the integration itself," Raban said. "We provide the licensing for the thermal inkjet, and those companies that really know integration will integrate that into different print engines."

**FIGURE 4**

**This thermal inkjet and laser marking tablet and capsule handler accommodates about 100,000 tablets or capsules per hour. One controller can orchestrate up to six handlers simultaneously.**

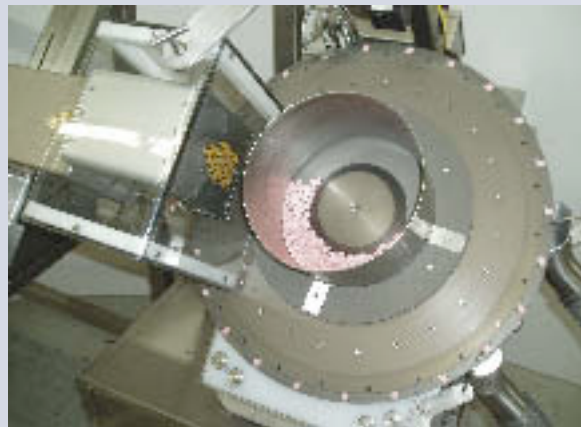


Photo courtesy of Efficient Automated Machine, Long Island City, NY

HP's existing inline coding partner, Inc.Jet, has built a robust thermal inkjet print engine for industrial applications. EAM has developed the tablet, caplet, and capsule handling machinery that "grabs" and positions the product for printing and inspection. See Figure 4. And Luciano Packaging Technologies, Somerville, NJ, is bringing it all together by integrating the component systems.

For vendors outside of the HP fold, a trend is to partner with companies that specialize in the formulation of inks. For example, Xaar is working with Sensient Pharmaceutical Technologies, South Plainfield, NJ, to develop inks for piezoelectric inkjet printing.