



The Business of Packaging

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Anti-counterfeit strategy needs interdisciplinary approach

- Written by John Spink, Director, Anti-Counterfeit and Product Protection (A-CAPP) Initiative

To develop and implement successful anti-counterfeit strategies, you need more than good technology.

You have to educate yourself and connect inside and outside your company. A good strategy needs the kind of interdisciplinary approach that you see in educational programs of IoPP and in our activities at Michigan State University.

A seemingly constant stream of high-profile counterfeiting incidents is raising awareness of consumers, regulators, enforcement agencies, and brand owners. In addition, product counterfeiting is not just limited to luxury goods or lifestyle drugs. Look at the counterfeit additive melamine in both pet food and milk. And remember counterfeit branded toothpaste in dollar stores.

Packaging managers get the task of finding anti-counterfeit solutions, but a successful action is an extremely interdisciplinary endeavor. Regardless of your experience and intellect, there will be aspects of the solution that you don't know.

For example, you may know about intellectual property rights law as it applies to a bottle design in the United States. But you might not have any experience prosecuting similar cases in Cambodia. You may have experience reducing product tampering, but not in deterring container theft in international free trade zones.

The range of disciplines

To deal with the complex nature of counterfeiting, the interdisciplinary approach reaches out to a number of areas. In our MSU Anti-Counterfeit and Product Protection (A-CAPP) Initiative, we look at these disciplines to develop insights:

- Criminal Justice gives us a perspective on the criminals and the crime.
- Social Anthropology provides a perspective on how businesses interact with each other in the source economies.
- Consumer Behavior helps us understand the demand.
- International Law shows when lawsuits are possible or a deterrent.
- Retailing helps us understand how the product could be authenticated.
- Packaging gives us the solutions once we understand the drivers around counterfeiting or diversion activities.

Using an interdisciplinary approach is not a novel concept for packaging managers. This profession is built from a wide range of applied technologies. For example, if a packaging manager is asked to double the shelf-life of a food product, the first step is not to just double the thickness of the package. We engage disciplines such as food science to understand how the food spoils and materials science to understand the mass transfer properties of the packaging material.

In developing an anti-counterfeit strategy, we are not dealing with E. coli, which has a biologically programmed method of operation. We are dealing with humans who are intelligent, resilient, persistent, creative, adaptable, and very motivated. It is dangerous to assume that we packagers can develop and implement an anti-counterfeit strategy alone.

An example of the interdisciplinary approach is in the steps taken to understand the types of counterfeiters and the types of counterfeiting. The overall strategy is built on the Criminal Justice concept of the “crime triangle.” It embraces the criminal, victim, and opportunity. The concept focuses actions to disrupt specific criminals or opportunities. You want to make sure to take actions that hack at the roots of the problem. For example, seizing 2 million counterfeit parts keeps that product out of the marketplace, but did it do more than just temporarily disrupt the counterfeiters’ cash flow?

The interdisciplinary approach looks for real progress rather than a “ready-fire-aim” approach that may look like you are doing something. Today’s counterfeiters are too skilled and “just any action” will no longer be effective. Relying just on your own experience and intellect will expose your company to additional risks. To only understand and quantify the many aspects of the counterfeit product threat is to be half-way to an effective and efficient solution.

About the author: IoPP member John Spink MS, CPP (SpinkJ@msu.eduThis email address is being protected from spam bots, you need Javascript enabled to view it) is an adjunct faculty instructor and the director of the Anti-Counterfeit and Product Protection (A-CAPP) Initiative at Michigan State University.

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Authentication—are brands under siege?

- *Written by Pat Reynolds, VP/Editor, Packaging World*

A pervasive air of secrecy makes trends in brand protection tough to track. But three authentication efforts shed light on some of the solutions being explored.

Brand owners beware: Counterfeiters, diverters, and gray marketeers appear to be broadening their horizons.

“Drug companies, manufacturers of consumer electronics, and marketers of high-end perfumes have been inquiring about brand-protection solutions for years,” says Ken Branch, principal of **Latitude 49** (760/972-7676), a security assurance company active in brand protection solutions. “The bad guys saw such products and packages as the low-hanging fruit. But now I’m hearing from packaged goods companies that make everything from food to motor oil. Any brand with value seems to be a target.”

At cosmetics manufacturer OPI Products, the threat to brand security comes not in the form of counterfeiting but rather by way of diversion. Randy Allen, vice president of operations at the North Hollywood, CA, firm, explains how diversion plays out in OPI’s world.

“We make product and sell it to licensed distributors who sell to beauty supply chains, beauty supply stores, or salons—with an applicable markup. If a distributor selling 10 bottles per salon sees a chance to sell 10,000 bottles to one mainstream retailer, that distributor may be tempted to discount the cost per bottle to the retailer and roll

his inventory. He doesn't get the high markup he gets by selling to salons, but by selling to a mainstream retailer in such high volumes, he's more profitable than if he sold through approved channels. But he hurts the professional salon owner or nail technician for whom our products are made because they are badly undercut on price by a large retailer around the corner. That's what we're up against."

Allen is working closely with a number of ink suppliers and manufacturers of marking and coding equipment to come up with better anti-diversion solutions that are covert in nature. He sees special promise in infrared inks and what he calls "narrow-spectrum readability." He explains.

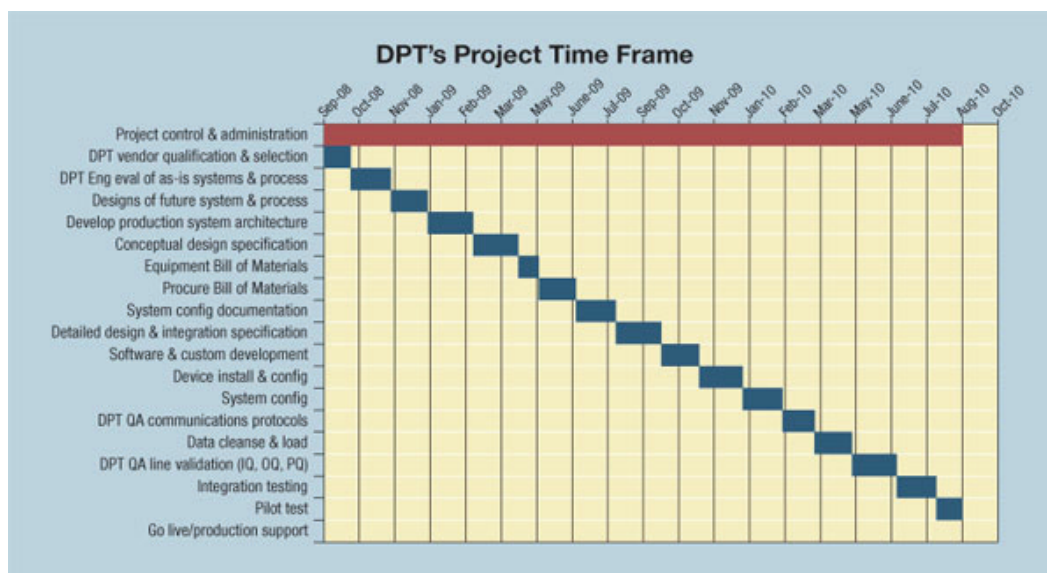
"Infrared inks are basically in the ultraviolet family. Unlike a broad-spectrum UV-type light such as black light, which makes everything readable, infrared inks are only excited and made readable by a narrow range of light frequencies. Ink manufacturers are currently looking at thousands of light frequencies that will excite only certain inks. As this work moves to commercialization, we'll have a new crop of covert marking solutions at our disposal."

The other key strategy that Allen is exploring is to incorporate a covert diversion-tracking code within the batch code. This twin code would be ink-jet-printed on a label that goes on the bottom of OPI containers. If diverters discover this code and try to remove it, they'll be tampering not only with a diversion-tracking code, but also with a batch code that is incorporated into the diversion-tracking code. Removing a diversion-tracking code so that product can be diverted is not illegal, but defacing a batch code is.

"That takes it out of civil court and puts it into the criminal court system," says Allen. "That's huge, because in criminal court, the identity of the distributor who is doing the diverting will be revealed. That doesn't happen in civil court cases that we bring against a retailer selling diverted product."

Securing the chain of custody

Pharmaceutical manufacturers have a real brand-protection battle on their hands, as the World Health Organization estimates that counterfeit drug sales could reach \$75 billion by 2010. For contract packagers, implementing a successful anti-counterfeiting strategy is especially challenging, says Alan Green, logistics director for DPT Laboratories, a contract developer of molecules as well as a contract manufacturer and packager that handles creams, liquids, gels, and powders.



“As contract manufacturers, we have to be all things to all people,” says Green. “And our customers are all over the map when it comes to what they think they need in the way of anti-counterfeiting measures. To further complicate things, we have a marketing arm with their own-brand product called Healthpoint. At the end of the day, we face a lot of opinions about what’s best and what isn’t. We have to listen to all of them.”

DPT is in the final stages of developing and implementing what might be called a pay-as-you-go plan. A 2D datamatrix bar-code track-and-trace system that goes right down to the smallest saleable unit will be the standard offering. On cases and pallets, the standard offering might be an RFID tag, so that when those cases and pallets come to a major distributor or wholesaler’s warehouse, they can be easily checked. But if a customer wants to go beyond the standard offering—suppose, for example, they want both a bar code and an RFID tag on individual units—DPT is looking at a menu of options that can be selected and paid for accordingly.

Green says the plan is to focus on prescription drugs first, though DPT also handles over-the-counter items. Partnering with DPT on the supplier side will be **Blue Vector** (www.bluevector.com) and either **SupplyScape** (www.supplyscape.com) or **Axway** (www.axway.com). DPT hasn’t gone commercial yet with its e-pedigree implementation. But here’s an illustration of how it might play out if tubed products, for example, are in production.

Each tube is assigned a unique serial number by either DPT or the contract customer. This number is carried in an RFID tag or 2D bar code on a pressure-sensitive label on the tube. Onto the corrugated case into which 12 tubes are to be inserted an operator applies an RFID tag; again, it’s carried on a pressure-sensitive label. As tubes move onto an accumulation table, a Blue Vector scanning device reads the 2D bar code or RFID tag on the tube and another Blue Vector scanning device reads the RFID tag on the case. So as the tubes are manually loaded into the case, Blue Vector software associates the 12 unique tube numbers with the tag on the case.

Later at DPT, the cases are put on a pallet and a Blue Vector reader associates the cases with a linear bar code or RFID tag that goes on the pallet. Finally, pallets are aggregated into an order. So a complete child/parent relationship linking tubes with cases with pallets with an order has been established.

While Blue Vector’s contribution is on the capture of the unique serialization numbers, SupplyScape’s or Axway’s e-Pedigree data management software is responsible for managing the chain of custody as the uniquely serialized product makes its way through the supply chain. Every time product changes hands—from drug manufacturer to DPT to Wholesaler 1 to Wholesaler 2 to Distributor—the unique identification numbers are sent into DPT’s Enterprise Resource Planning System (ERP). When the e-pedigree is built, the unique IDs are extracted out of ERP—along with all the other information that’s required, such as manufacturer’s name, lot code, expiration date, invoice number, etc.—and electronically sent to the next trading partner in the chain.

“On the packaging line and at the distribution center, Blue Vector’s technology is the vehicle by which we capture and authenticate the serialized numbers that go out the door,” says Green. “Their software rolls that data up into our business system and ultimately into our ERP, and that’s where the e-pedigree provider takes over. They take the pedigree information and collect the serialized number and keep that database and send that pedigree to the next owner of the item.

“The way we look at it, an anticounterfeiting solution is going to be a requirement in the very near future. Like putting a cap on a bottle, it’s simply something that’s done.”

What about repackaging?

Like DPT Laboratories, Med-Health Pharma operates in the pharmaceutical industry, too. But Med-Health Pharma is a repackager, not a contract packager.

Located in North Las Vegas, NV, Med-Health Pharma also has an ambitious e-pedigree plan in place, and it's similar to DPT's in that it includes SupplyScape as the provider of the chain-of-custody software. But before delving into how it works and who some of the other suppliers are, it's useful to understand what kind of repackager Med-Health is. Or perhaps "will be" would be more accurate, as the firm is gearing up for a third-quarter launch in 2009. Even so, we'll stick to the present tense here for purposes of simplicity.

The bottles that Med-Health Pharma repackages are for sale primarily to doctors. Bottles hold 10 to 30 doses, and the only drugs involved are the kind that are commonly prescribed by general practitioners for common ailments. It's a relatively new concept known as "point-of-care dispensing," which, as the name suggests, means patients receive their prescription drugs right in the doctor's office—the point where medical care is given—instead of having to make a second trip to a pharmacy.

Med-Health Pharma buys the drugs in 100-count bottles from Med-Health Pharmaceutical Products (MHPP), a pharmaceutical wholesaler that's right down the street from Med-Health Pharma. The two are allied, but Med-Health Pharma is still a separate and independent company. MHPP deals primarily in generics from drug makers such as Watson or Westward.

At Med-Health Pharma, bottles sent by MHPP are opened automatically on a machine from **Bellatrix** (www.bellatrix.com) that automatically opens bottles and cuts the bottoms off so the contents can be emptied into a bin. "The machine was originally developed," says Med-Health Pharma director of operations Mark Hames, "for drug manufacturers who, due to a labeling mistake or cocked caps or some other flaw that made a container not suitable for shipment, needed to send large numbers of bottles through rework. But it meets our needs perfectly."

Med-Health Pharma stores the bins of pills in inventory until an order for them comes in. At that point, the pills are taken into a packaging suite where they are repackaged into patient-sized high-density polyethylene containers holding anywhere from 10 to 30 doses. These are sold back to MHPP for sale to doctors.

When Med-Health Pharma swings into production, three brand-protection strategies will be deployed, says Sam Haddad, vice president of operations. One is from **Kodak Security Solutions** (www.kodak.com), whose Traceless System for Anticounterfeiting taps into a wide array of Kodak's intellectual property and expertise in material science, digital imaging, and printing. In Med-Health Pharma's case, a taggant is involved. It's delivered to Med-Health Pharma embedded in the thermal-transfer ribbon that gets fed to a **Sato** (www.satoamerica.com) print engine. The print engine is mounted on a pressure-sensitive label unwinder from **Herma** (www.herma.co.uk), which in turn is mounted on an Eco-Wrap wraparound labeler from Bellatrix.

When the pressure-sensitive label runs through the Sato print engine, it receives the Traceless covert taggant as well as the human-readable copy and graphics that are required on the label. The taggant can only be viewed through a laser-based reader.

"If any bottle with labeling that identifies it as ours should ever be a cause for concern in the marketplace, we can scan the label with the Traceless System reader to verify whether or not it's an authentic bottle that came from

one of our production runs,” says Haddad.

The Sato print engine also imprints on each p-s label a unique ID, generated by **Yottamark** (www.yottamark.com), that's printed in two formats: a 24-digit human-readable code and a 2D datamatrix bar code. Yottamark's encryption engine securely generates unique serial numbers that can't be repeated.

“It's not that we prevent copying,” says Yottamark's Elliott Grant. “But counterfeiters have no incentive to make one fake. They need to make an abundance of fakes to make any money. So with our technology, you're looking for patterns of duplicates showing up in the field. If the same code ever shows up twice, we know there's a problem because our algorithm can't generate the same unique code twice. So we catch you if you try to make up a number, we catch you if you try to copy a bunch of numbers and seed them in the marketplace, and we catch you if you try to reuse numbers that have already been used.”

The third brand-protection strategy used at Med-Health Pharma is the e-pedigree data management software system from SupplyScape, which operates in a manner similar to what we saw in DPT's case.

OPI, DPT, and Med-Health Pharma are just three of the many firms now coming to grips with the challenge of brand authentication. It's a problem that won't be going away anytime soon. Look for ongoing updates and insights from Packaging World as they become available.

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Nanotechnology and food

- *Written by Jay Singh, Associate Professor and Packaging Program Director, Cal Poly State University*

Nanotechnology holds great promise in the food packaging arena.

Lightweighting, improved recyclability, strength improvement, monolayer structures with multilayer capabilities, improved barrier properties against environmental factors, increased shelf life, encoding or decorating individual surfaces, counterfeit protection, smart substrates that can sense and signal food contamination or spoilage within or outside a package—these are among the possibilities nanotechnology offers. No wonder one study suggests that the U.S. nanomaterial market, which totaled only \$125 million in 2000, is expected to reach \$1.4 billion in 2008 and to exceed \$30 billion by 2020.

The importance of this technology among researchers from industry and academia was evident at the recently concluded 16th International Association of Packaging Research Institutes (IAPRI) World Conference on Packaging. Held in Bangkok, it featured presentations by some of the most dynamic researchers from around the world. No less than 30 presentations and posters at the conference discussed nanotechnology-based materials, including:

- Cellulose-based and zein-based micro and nano-fiber infused nanobiocomposite films
- PET/Fish gelatin nanoclay composite/LDPE laminate
- PLA/epoxidized natural rubber/organoclay nanocomposites
- Reinforcement of starch based resin by hemp fiber
- Bionanocomposites based on cellulose nanowhiskers and renewable polymeric matrices

- Thermoplastic cassava starch films
- Calcium carbonate as filler for PLA/starch blends
- Chitosan/montmorillonite coated paperboard
- Aluminum oxide coated PLA films

Both industry and academia are hard at work trying to unlock the benefits that could eventually be realized if the above technologies are “perfected” and commercialized in the world of packaging. And don’t forget that these benefits would accrue to manufacturers and consumers alike. Here’s just one example: Nanotubes (cylinders with 10 to 150 nm diameter and lengths of 500 to 15,000 nm) might be the missing ingredient to help strengthen the physical properties of compostable plastics such as polylactide acid (PLA) as compared to traditional plastics.

As it stands today, nanocomposites are generally too expensive or too impractical to implement on a commercial scale. But as development in this area continues, application of nanotechnology to food packaging is sure to increase. Improvements in safety and functionality are key drivers. We should not forget, however, that consumer opinion and the approval of the regulatory bodies—which are scientifically rigorous and extraordinarily complex—will have a powerful impact on how this all shakes out.

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Reigning in the rogues

- *Written by Pat Reynolds, VP/Editor, Packaging World*

With the exception of an infectiously joyous masterpiece known as “Where the Hell is Matt,” I’m no fan of YouTube.

Why do so many people think anyone cares about the stuff that shows up in all those grainy, user-generated video clips?

But recent research into the subject of packaging’s role in brand protection and anti-counterfeiting led me to a YouTube offering I’d highly recommend (www.youtube.com/watch?v=83xPn9b32ts). Called “The genuine danger of counterfeit medicines,” it was commissioned by EFPIA, the European Federation of Pharmaceutical Industries and Associations. It’s a serious examination of an increasingly serious problem.

Some of it covers familiar territory. Like the part about 500,000 fake medicines being seized by EU Customs in 2005 and how, just two years later, that number had exploded to 4 million. Or the part about the World Health Organization and its estimate that more than half the drugs sold over the Internet are fakes. Or the segment where an Eli Lilly & Co. representative shows how difficult it is to tell an authentic carton of the antidepressant Zyprexa from a counterfeit carton. “The quality of packaging on the counterfeit is really remarkable,” he says.

The part of the video that is not familiar territory is the part that covers the EFPIA Product Verification Project. This ambitious project seeks to establish a standardized identification solution for pharmaceutical products across Europe. It’s driven largely by the growing number of dosing and dispensing errors at pharmacies and hospitals and by the alarming growth of counterfeits in the legitimate supply chain.

Why is this video of special interest to packaging professionals? Because the EFPIA solution discussed in the video is so packaging-centric. It hinges on a unique 2D bar code placed on packages that can be scanned by pharmacists at the point of dispensing anywhere in Europe. Its emphasis on 2D bar codes is not to say it's biased against RFID. Consultant Paul Mills, who has been tasked by EFPIA with the responsibility of pulling together the track-and-trace technology underpinning the project, puts it this way.

“RFID adds some complexity compared to relying on a 2D bar code as the carrier. But the Product Verification Project is carrier-agnostic. There's been so much focus on the carrier technology, i.e., RFID versus bar code, when it might be better to rise above that and think about what business objective we're trying to solve. Why not look at the data content and worry about the carrier as a separate issue?” (Listen to Mills discussing the EFPIA verification project at www.packworld.com/podcast-26157.)

Carrier issues aside, what's compelling about the Product Verification Project is that the EU is wisely discouraging, in its pan-European approach, a proliferation of coding solutions developed by various EU member states. The implementation of such coexisting solutions, EFPIA points out in its Web site, “constitutes an obstacle to enhanced tracing and tracking of medicines at an EU level and adds production costs to manufacturing.”

Why do we not see a similar approach being taken in the U.S.? Why is the California Board of Pharmacy allowed to go rogue by developing its own solution when what's clearly needed is a solution at the federal level? Why doesn't the FDA rein in the Californians and develop a sensible solution that works as well in Maine as it does in California?

Such questions, fortunately, are being asked with increasing frequency by a variety of pharmaceutical industry stakeholders. Answers, though probably slow to come, may bring about a drug authentication/verification system for the U.S. that's suitable from sea to shining sea as opposed to a hodgepodge of solutions applied on a state-by-state basis. In the meantime, keep an eye on EFPIA's identification project. Plugged-in observers are betting that it's a precursor to a global initiative.

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Catalent expert addresses turnkey serialization



- *Written by Jim Butschli, Features Editor, Packaging World*

Catalent Pharma Solution's Akan Oton provides a contract manufacturer/packager's perspective on serialization, authentication, and track-and-trace technologies in pharmaceutical distribution.

Maintaining electronic pedigrees of your pharmaceutical products through the distribution chain is a challenge for most manufacturers. Now imagine tracking products for and with about 250 pharmaceutical companies. That's the task that will face **Catalent Pharma Solutions, Inc.** (www.catalent.com) when e-pedigree regulations are in place. Formerly Cardinal Health's Pharmaceutical Technologies and Services Div., Catalent provides development, manufacturing, and packaging services for pharmaceutical, biotechnology, and consumer health companies in nearly 100 countries.

“We're the largest contract packaging, drug development, and contract manufacturing organization in the world,” said Akan Oton, Catalent's global marketing director. Oton addressed an audience of about 115 at the April 8

Brand-Protection Packaging Forum (www.packworld.com/bppf) in Schaumburg, IL. The following insights from Oton come from that presentation.

Technology options compared		
	Pros	Cons
2D barcodes 	<ul style="list-style-type: none"> • Inexpensive to set up and use • Use around biologic drugs • Can be printed on any substrate 	<ul style="list-style-type: none"> • Need line of sight to be read
RFID 	<ul style="list-style-type: none"> • Preferred by distributors because it simplifies their operations • Does not need line of sight to be read 	<ul style="list-style-type: none"> • Expensive to set up and use • Failure rate of tags • Low read rates around liquids and metals • Cannot be used around biologic drugs (FDA decision)

- As contract packagers, we are concerned about counterfeiting in the industry, and we intend to put in place track-and-trace solutions in our facilities to help manufacturers stem this.
- One of the big challenges is not as much how to package products but how to apply track-and-trace on packaging lines at high rates and subsequently ensure integration with multiple IT systems.
- In the clinical trial supplies portion of our business, when we procure drugs for comparative studies for customers, we also need to make sure they're not counterfeit. We've got a lot of analytical support to make that determination as the impact to our customers is considerable given that the average pharmaceutical company spends about \$800 million developing a drug.
- We started pilot testing RFID back in 2002 to get a handle on the robustness of the technology, read rates, scrap rates, etc. I don't see a major difference between RFID and serialized bar codes from a manufacturer's point of view. They are complementary technologies. Whichever works better in your firm is the one you should choose. From a distributor's point of view, RFID clearly has advantages as it does not have a line-of-sight requirement.
- Legislators want a unique number on each product that must pass down the distribution chain to create a pedigree for that product. Legislators aren't telling us how or what method to use. However, for serialized bar codes, because of the line-of-sight requirement, you have to create parent/child relationships, so that what's in the box is the same as what's on the label, and on the case. This allows distributors to "infer" what is inside.
- In deciding whether to use preprinted or coded tags, our preference is to print or code at the packaging line because it's more controllable, particularly in high-speed operations. For lower-speed or smaller-scale processes, I think you can do it offline in a preprinted manner. Once you get to bottle lines that run at 300/min speeds, it's more efficient to print or encode at the line.
- Many decisions being made in the pharmaceutical industry regarding packaging equipment and tracking are going to change in the next two years based upon equipment providers getting more up to speed on performance

levels when it comes to tracking.

- Because the pharmaceutical business is FDA-regulated, you should keep data on your products for five to seven years. That's a challenge when you're talking about putting a number on each bottle and storing that information, especially for us with multiple products from about 250 customers.
- To store some of this information, we work with a company that provides serialization databases to generate individual package numbers. These databases must be auditable. A concern of ours dealing with many customers and different databases is making sure that one customer's number isn't the same as another's, so considerable thought went into making sure our approach to generating numbers was unique for all customer products. The unique codes are then transmitted to the customer's certified **EPCglobal** (www.epcglobalinc.org) e-pedigree partner. It is this partner that creates the actual pedigree for the manufacturer.
- Although we're agnostic when it comes to the selection of 2D bar codes or RFID, there are some limitations to both. Today, RFID tags do have modest scrap rates. Although the tags aren't as reliable as we'd like, we expect they soon will be. In the distribution environment today however, 99.9% isn't good enough. It needs to be higher than that at the item level. At the case level, that number is more than fine. If you're working with liquids, RFID read rates won't be suitable—opt for 2D bar codes. And if you're working with biologics, where there could be stability issues associated with radio frequency, you should utilize 2D bar codes. In terms of 2D barcodes, the primary limitation is lack of line-of-sight and the need for inference.
- We have a relationship with **Secure Symbology** (www.securesymbology.com), in which they host data for you, will generate numbers, and will work with you on RFID tagging and 2D bar codes. In concert with Catalent, this provides a complete serialization solution.
- With RFID technology, we looked at just about every vendor out there. We chose **Alien Technologies** (www.alientechnology.com). The failure rate on their UHF Gen 2 tags is low, and their next-generation products appear to be better than those from competitive companies that we have seen so far.
- In the pharmaceutical business, it's all about compliance and making sure everyone in the distribution chain is protecting patient safety.

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Many sources of advice on enhancing supplier reliability

- Written by Eric F. Greenberg, Attorney-at-Law

Food packagers always face challenges, of course.

But what might be called a new generation of modern challenges has lately been occupying the attentions of industry, government, and academic food experts.

Modern challenges, like the threat of terror or counterfeit or substandard ingredients and products, raise an important question for food packagers: What, if anything, do I do to protect my company that I am not already doing?

Soon after the 9/11 attacks, FDA issued guidance documents to help importers and others in the food chain of commerce evaluate how they might harden their practices against intentional contamination. These recent efforts appear to be inspired by a broader set of concerns, including the prospect of terror tampering, yes, but also economically motivated quality issues and product counterfeiting.

It has always been true that quality assurance practices and procedures are designed to protect your company by assuring that the product is made correctly first time, every time. From a regulatory point of view, these concepts are embodied in 'current Good Manufacturing Practice' principles, and, for some products like meat and seafood and juices, Hazard Analysis and Critical Control Point procedures, and scheduled processes for acidified and low-acid canned foods and aseptic packaging systems.

But with the intervention of some sad realities, food makers and others had to start rethinking what they did to confirm not just the quality of their product, but its safety as well. The specter of terrorist interference with the food supply, and the reality of supplier unreliability especially regarding imported products and ingredients, have intruded to make packagers rethink what they do.

And the focus is more on the products and ingredients that they take in, rather than on what happens within the four walls of their own facilities.

Happily, there are excellent sources of assistance for companies large and small tackling this problem. The most recent, and sure to be among the most influential, is a "Food Supply Chain Handbook" from the Grocery Manufacturers of America.

The GMA is the largest trade organization for the grocery industry. In October of last year, they held a meeting in Washington, D.C. to gather ideas on attacking these issues. Over 150 attendees participated, including manufacturers but also importers, retailers, regulators, and trade officials.

As a result of such varied perspectives, the group was able to identify the most important issues and the most practical ways to address them.

The workshop confronted participants with several key questions:

- What programs should suppliers have in place to meet customer requirements for safety and security?
- How can buyers best verify the integrity of the products purchased and how frequently should this be done?

- How should the food industry best share testing results with the federal and or state agencies?
- What is needed to ensure letters of guarantee and certificates of analysis are meaningful and accurate?
- What are the components of and how should buyers implement a second and/or third party audit program?

The resulting handbook, which at press time was still in draft form, is a start-to-finish enumeration of recommendations to allow those in the food and beverage chain of commerce to evaluate their practices and make improvements where they seem warranted.

Not surprisingly, management of one's suppliers is a major topic. Particularly where the concern relates to imported product, simply assuming that a supplier who guarantees the quality of its product will deliver every time is less possible than in the past. Product purity and quality are harder to consistently assure when the sources of supply are varied. And your foreign source might be more a broker than a factory, so even if you order from one entity you might be receiving product from a range of sources, sometimes without knowing it.

Some participants in the program also advocated a point of view that is desirable to have suppliers who have a complex and sophisticated understanding of regulatory requirements. Rather than only asking for certain specifications to be met or confirming them once the product is received, it's often a good idea to stick with suppliers who can demonstrate to you that they understand the regulatory requirements in the first place. Amplify that with written documentation in the form of certificates of compliance and technical specifications, and you will have improved your measures of assurance.

Other segments of the handbook appear to cover similar ground to the good manufacturing practices regulations, addressing sanitation issues, employee training and label control programs.

FDA is certainly active in this area. In March, Dr. Stephen F. Sundlof, director of FDA's Center for Food Safety and Applied Nutrition, told Congress that "changes in consumer preferences, changes in industry practices, and the rising volume of imports have posed challenges that required us to adapt our current food protection strategies."

FDA is now asking Congress to give it greater authority to see documents during food facility inspections—right now they have access to such records if they have a reasonable belief that the food is adulterated and presents a threat of serious adverse health consequences or death. FDA wants to eliminate that requirement for a reasonable belief the food is adulterated, and they want access to records of related food products, too, such as those produced on the same manufacturing line. They also want the power to order companies to recall foods.

As for imports, FDA is hoping to change the focus from merely checking on the compliance of imported foods to helping assure that quality products are manufactured overseas in the first place. The agency has already put in place cooperative agreements with the Chinese government, and this emphasis on GMPs by foreign manufacturers should help reduce the quantity of violative products in the first instance. It is philosophically similar to industry efforts to pressure suppliers to be familiar with and comply with regulatory requirements.

One way manufacturers keep the pressure on their suppliers is by demanding that the suppliers issue letters guaranteeing the compliance of the products or ingredients they supply.

Though letters of guarantee passed down the chain of commerce are a common practice within food and

packaging businesses, companies don't always understand their full implications. When you receive a guarantee letter from a supplier that guarantees its product complies with the Food, Drug & Cosmetic Act, a common question is whether one should take any further steps to confirm whether that representation is accurate?

The legal answer is that you aren't required to. But the prudent answer, depending on the situation, is often "yes you should." After all, what the law requires of you is that you assure that all the product you put into commerce is in compliance with law, not adulterated or misbranded. The guarantee letter is simply a commercially common measure to allow different players to get the assurances they need that the product is in compliance. (It also can protect some players from FDA prosecution for trafficking in adulterated or misbranded products, but only in limited circumstances.)

However, it is often a good idea to take further steps, call them due diligence, to confirm the letters' information. This can include demanding laboratory analysis of the product or conducting it yourself; asking for additional details about the product formulation; and even, on a longer term basis, inspecting the supplier's facility and learning their level of sophistication in terms of compliance issues.

When it comes to packaging materials intended to contact food, it is also important to remember that while a supplier might issue a guarantee letter about a particular product, it is the intended use of the product that really matters, and it is important to assure that your intended use is within the scope of the conditions of use that the guarantee covers.

Dr. Craig Henry, senior vice president and COO for Scientific and Regulatory Affairs at GMA, was a central figure in the development of the handbook. He emphasizes that now, as the handbook is being finalized, GMA believes that industry has to take responsibility for what they buy and sell. He says that various companies' commercial clout should be used to eliminate "high risk" products and producers. The effort and money needed to do this will offset the damaging costs and loss of goodwill associated with product recalls, reductions in consumer confidence, and in enhanced pressure from Congress.

One group is emphatically bringing together industry, government and academics to attack counterfeiting and similar economic hazards. John Spink, M.S., Faculty Instructor at the Michigan State University Food Safety & Toxicology Center, is spearheading the Packaging for Food and Product Protection Initiative. Its goal is to attack the product counterfeiting monster, combining packaging, food, drug, medical devices, general consumer products, chemicals, auto parts suppliers, and other industries, along with government agency personnel and other academics.

Spink says many companies are well along working on various anticounterfeiting strategies, but they can't discuss them because they are, necessarily, confidential. He says that having an academic setting helps allow the development of these ideas, particularly when each product industry wants to hear what the others are doing. The Initiative's work has begun, and the organizers will present a course this Summer on Packaging for Food and Product Protection.

Kenya tackles drug counterfeiting

- Written by Denis Gathanju, Contributing Editor, Packaging World

Health officials and drug manufacturers alike are developing ways of keeping counterfeit drugs from becoming what some would call 'a healthcare catastrophe.'

A two-year-old boy is rushed to a Kwale hospital in Kenya's Coast Province. The clinical officer at the health facility diagnoses febrile convulsions and quickly rushes to the hospital's pharmacy for a dose of medicine that will ease the boy's suffering. But nothing happens, so the boy is given additional doses but still the boy does not respond. Finally, he dies. Only later, upon investigation, is it discovered that the drug had no active ingredients. The drug was a fake.

Counterfeit drugs in Kenya have been known to exist for a long time. Walk into any pharmacy in search of a certain drug prescribed by a doctor. If the price is too high, the pharmacist will tell you of yet another prescription drug that works just the same but comes cheaper than the one requested.

"There is no difference whatsoever," he is quick to say, "the prescription is the same, the difference is just the manufacturing company," he adds as he quickly wraps the cheaper drug.

The magnitude of the sale of counterfeit drugs was felt several months ago when a popular anti-malarial drug was discovered to be a fake. Officials from the Pharmacy and Poisons Board, a government watchdog that registers pharmaceutical firms and pharmacies, discovered thousands of fake anti-malarial drugs stashed in a downtown Nairobi electrical shop.

Shocked by the discovery, Beijing Holley Cotec, the Chinese company that manufactures the popular artemisinin-based drugs Cotecxin and Duo-Cotecxin, immediately recalled all the drugs in the Kenyan market for analysis. The firm also elected to re-introduce the popular drugs, this time under strict packaging guidelines that would make it harder for counterfeiters to duplicate.

Duo-Cotecxin is one of the artemisinin-based combination therapy drugs that is highly recommended by the World Health Organization (WHO) in the treatment of malaria. The drug is widely supplied in government and private hospitals in Kenya.

According to the Kenya government's chief pharmacist Dr. Fred Siyoi, a full dose of Duo-Cotecxin costs about Kenya Shillings (Kes) 350 (US\$5) in Kenya while the counterfeited drug was selling for less than Kes 70 (US\$1) in Nairobi and elsewhere in the country.

A counterfeiting first

Speaking at a press briefing, the head of the Kenya government's anti-malarial control unit, Dr. Willy Akwale, said this is the first case of a counterfeit supply of artemisinin combination therapy drugs. Said Akwale: "There have been many counterfeits on the sulphur-based anti-malaria drugs before, forcing us to have difficulties in countering the disease."

Kenya's Director of Medical Services Dr. James Nyikal says the Ministry of Health is committed to ensuring that all drugs on sale in the country are safe and meet the established standards of quality and that inspection of fake drugs has been intensified across the country.

He says the Pharmacy and Poisons Board has set up an elaborate system for evaluating quality of drugs before and after registration for sale in Kenya.

According to Dr Wilfred Ochieng, head of Pharmaceutical Inspectorate, the Pharmacy and Poisons Board regularly samples medicines on sale in the market and analyzes them at the National Quality Control Laboratories and at the University of Nairobi to ensure that they adhere to established quality standards. He says the board has posted drug inspectors at all ports of entry to control entry of medicines into the country.

Quality analysis done by the Pharmacy and Poisons Board on the discovered counterfeit anti-malarial drugs showed that they did not contain the active anti-malarial ingredient and cannot therefore be used in the treatment of malaria. The board immediately issued a public alert in the local press and gave guidelines on how one could tell the fakes from the genuine drugs.

Says Dr. Siyoi: "From outside, the counterfeit pack looks similar to the original product and may be difficult to tell apart. Some packs even bear a batch number similar to one of the genuine batches officially supplied last year."

Contrary to what is stated on the label, notes Dr. Siyoi, the counterfeit products have not been manufactured in the facilities of Beijing Holley-Cotec Pharmaceuticals, the sole license holders and manufacturers of Duo-Cotecxin and Cotecxin. He says there are differences between the packaging containing the genuine and counterfeit drug. The difference is on the blister pack, where the name of the manufacturer is indicated on the genuine pack but not on the pack holding the counterfeit.

Another difference that Dr. Siyoi identifies is that the printing on the blister pack containing the counterfeit drugs fades easily on rubbing with a moist finger. On a package of the genuine drug, this does not happen.

Investigation is ongoing

Dr. Nyikal says investigations and inspections are ongoing to determine the extent of the distribution of the counterfeit Duo-Cotecxin and Cotecxin drugs. The goal is to identify individuals or companies behind the sale of the counterfeit drugs. In a recent interview with the press, Eric Law, Beijing Holley-Cotec Pharmaceutical's vice president, says that they have yet to locate the source of the counterfeits, but there is strong evidence linking the source to Asia.

"We are going to introduce a new technology to bring tamper-evidence to doses that will be supplied to replace the withdrawn drugs," Mr. Law told the press.

The Chinese drug manufacturer recalled more than 20,000 doses of the anti-malarial drugs from the Kenyan market and will replace them with new drugs in new tamper-proof packaging that has a three-dimensional hologram seal on the outer pack. "Make sure you find this hologram on the packaging," Law advises. If the packaging does not come with the hologram, he says, then the drugs are not genuine. According to Law, the new packaging will make it difficult for the cheats to replicate and sell fake drugs into the Kenyan market, where more than 35,000 people die of Malaria each year.

Martin Kimani, the Kenya sales executive at Beijing Holley-Cotec, says the discovery of the fake drugs in Nairobi was a great eye-opener for the firm, which will now constantly check on its products put in the marketplace. In a telephone interview, Kimani indicates that a packaging security solution in addition to the three-dimensional seal has also been deployed. But he would not divulge details. Neither would he give details on the losses the firm has incurred following the sale of the counterfeit drugs.

“With the new security packaging we have introduced, we are a few steps ahead of the counterfeiters,” he says. Kenyan health officials warn of a global health catastrophe if the growing trade in fake anti-malarial drugs leads to widespread resistance. Making matters worse, sophisticated trans-national gangs are thought to be behind the counterfeit drugs, a fast growing multibillion-dollar business.

Counterfeiters have made a killing in Kenya’s war on Malaria and have also greatly benefited from the booming sale of erectile dysfunction (ED) drugs as well. In the summer of 2007, it was discovered that the popular drug Çialis was a hot sell. Counterfeiters jumped at the opportunity, much to the amazement of the Pharmacy and Poisons Board. Çialis’ manufacturer Eli Lilly says the counterfeiters in the local market have reached levels that have drastically undermined their trade in the country, forcing the pharmaceutical firm to adopt a new security packaging system.

“Barely six months after the launch of the drug in Kenya, illegally imported Çialis had eroded 70 percent of our market,” says Steve Mburu, the firm’s marketing manager. “When we check with doctors and pharmacists, the sales are ever soaring, but this is never reflected in our books. It is not until doctors complained that our product was no longer producing the expected kick that we took a closer look. We saw a lot of fakes, counterfeits, and even some dangerous products masquerading as Çialis.”

New security pack

To fight the counterfeiters, the manufacturer recently introduced a security pack with four distinct features that include an oval sticker that looks different when the pack is viewed from different angles. Other security packaging measures put in place include tamper-evident seals and color-shifting ink logos.

Recently, the National Quality Control Laboratories (NQCL) and the Pharmacy and Poisons Board carried out a random survey of drugs in the Kenyan market and found that almost 30 percent of drugs are counterfeit. Says Dr. Hezekiah Chepkwony, the director of the NQCL: “Some of the drugs are no more than just chalk or water being marketed as competent pharmaceutical products.” The fake drugs, notes Dr. Chepkwony, range from dangerous products to totally ineffective ones.

Trade in counterfeit drugs is a lucrative business and the figures speak for themselves. According to figures from the Kenya Association of Pharmaceutical Industry, counterfeit pharmaceutical products account for approximately \$130 million annually in sales in the country.

“Counterfeiting is a plague in Africa; it is a crime to sell fake drugs and governments need to consider increasing penalties against the distribution and selling of counterfeit drugs,” says Karl Lintel, Pfizer regional director. Pfizer, says Lintel, has set up a department to deal with counterfeit drugs. The department is mandated to conduct regular check-ups in the market, and the company shares information with the relevant authorities so that the public is warned in time.

Many experts blame the country's legal systems for not being serious in fighting counterfeits.

"The penalties for such a criminal act are in most cases inadequate," notes Dr. William Mwatu, the medical and regulatory affairs director at East Africa GlaxoSmithKline. "We are currently seeing an increase in the hawking of medicines from pharmacy to pharmacy by unauthorized persons. We need to ensure that we sell drugs to authorized persons and buy only from authorized persons, if we hope to stop counterfeits," Mwatu explains.

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