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Ensuring Product Integrity and Trust in Your Supply Chain

October 5 2011 by Geoffrey R. Kaiser

A mother opens a jar of Gerber® mixed vegetables and begins feeding them to her infant daughter. A man buys a General Electric® microwave oven, plugs it into a wall outlet in his apartment and proceeds to cook a frozen dinner. A father withdraws the indicated dose from a bottle of Children's Motrin® to administer to his 8-year-old son, who is running a 102 fever. A woman wearing contact lenses opens a bottle of Bausch & Lomb® lubricating drops and squeezes a few drops into her eyes. A mechanic installs what he believes are genuine replacement BMW® brake pads on his customer's vehicle in time for a weekend road trip. A young girl waits expectantly as her parents present her with a new Barbie® for her birthday.

It would be easy to take for granted the enormous trust that is implicit in each of these actions. The trust that the baby food will nourish rather than sicken. The trust that the microwave oven will not explode when the power is switched on. The trust that the medicine will, in fact, reduce the young boy's temperature, and not cause it to spike. The trust that the lubricating drops will soothe, and not blind. The trust that the brake pads will reduce the vehicle's speed when force is applied, and not simply disintegrate on contact. The trust that the doll is not made with dangerous components that can cause injury or even death to a child at play.

are not yet there, then surely we have never been closer, as counterfeiters gradually insinuate themselves into our daily lives by marketing a dizzying array of counterfeit consumer products wrapped in increasingly sophisticated packaging that is difficult to distinguish from the real thing. Just imagine what it would mean to our way of life – and to the economic fortunes of brand owners — if we were no longer able to trust the branded products in our pantries, medicine cabinets and toy closets, to say nothing of home appliances and the cars we drive. Companies would wither and die, and consumers would lose their right to live free from fear. Life would become a daily game of Russian roulette, with consumer goods substituted for bullets. This places a profound responsibility on business leaders to do what is needed to secure the integrity of their products in order to protect their companies and customers.

For now, the best protection consumers have against falling victim to counterfeit trade is to ensure, to the best of their ability, that all of their purchases are made through manufacturer-authorized retail channels. That is because a brand owner’s control over its own supply chain remains the best assurance that the products bearing the brand owner’s trademark which are sold to consumers are authentic and meet quality standards. The farther that consumers stray from authorized distribution channels in search of “bargains,” the more likely they will wind up receiving more than they bargained for, in the form of counterfeit and substandard goods.

Yet, even sticking with authorized retail outlets is no guarantee of product integrity. The fact of the matter is that not all brand owners do, or can, exercise the same degree of care in securing their supply chains to ensure product integrity. Sometimes this is due to inadequate internal controls, but other times it is simply because brand owners lack the requisite control over other key participants in their supply chains. For example, a consumer walking into a CVS Pharmacy or Rite Aid reasonably expects any medication purchased to be genuine, relying as much on the legitimacy of those national retail pharmacy chains as on the trademark appearing on the product packaging. However, is such confidence really justified? A number of court cases arising in the pharmaceutical industry make this a fair question.

The case of Fagan v. AmerisourceBergen Corp., et al., illustrates how counterfeit goods can sometimes infiltrate even well-known, “legitimate” distribution outlets. In Fagan, the 18-year-old plaintiff, Timothy Fagan, was prescribed the anemia drug Epogen following a liver transplant. He had obtained the Epogen from CVS pharmacy, which had purchased the medication from AmerisourceBergen (“AB”), a wholesale distributor of pharmaceuticals. AB was an authorized distributor of Amgen, which manufactured Epogen, but AB also purchased Epogen and other drugs from secondary sources in the “gray market.” Two shipments of Epogen sent by mail from CVS to the plaintiff turned out to be counterfeit product which, although it contained the active ingredient, was only one-twentieth the strength indicated on the label. Fagan alleged that he was administered counterfeit Epogen for two months, and that this delayed his recovery from the liver transplant and caused continued anemia and pain. In declining to dismiss negligence claims against AB and CVS, the court took note of allegations that AB’s conduct in delivering and receiving medications to and from secondary sources fostered a “gray market” that traded in diverted or counterfeit drugs, and that CVS had known of drug counterfeiting and diversion activities since 1988 and might have purchased drugs on the “gray market.”

Lipitor that did not treat her medical condition, and that this counterfeit product had been purchased by Rite Aid from Albers Medical and another company. The facts showed that certain lots of Lipitor distributed by Albers Medical had, in fact, recalled after authorities uncovered a counterfeiting ring engaged in the manufacture of counterfeit Lipitor and illegal diversion of Lipitor not approved for sale in the United States. Ashworth sued Pfizer, the drug distributors and a drug repackager that had allegedly repackaged counterfeit Lipitor. The court dismissed the complaint against Pfizer.

Highlighting the limitations in supply chain security when dealing with counterfeits, the court in Albers Medical concluded that Pfizer was “not responsible for the manufacture, distribution or sale of the counterfeits and may not be held legally responsible for any claims arising from the physical manufacture, distribution and sale of the counterfeit products.” The court commented that “Pfizer, by virtue of its status as the manufacturer of the product that was counterfeited, does not become a marketplace insurer.” Further, the court rejected Ashworth’s claim that Pfizer should have regulated its authorized distributor to prevent infiltration of counterfeits, ruling that there was “no existing law, regulation or rule placing a duty on Pfizer to police its distributors” and that “Pfizer had no legal duty, at common law, to do so.” In other words, Pfizer had no duty to protect consumers against the risk that Albers Medical would sell Rite Aid counterfeit Lipitor that would eventually wind up in Tammy Ashworth’s bloodstream.

Other large consumer retail stores, such as the Costco and Sam’s Club warehouse chains, also have been sued for selling counterfeit goods, ranging from fake Fendi® handbags, to fake home exercise kits, to fake wall art. Safeway, the giant supermarket chain, was once sued for selling counterfeit Similac® baby formula. Cartier sued Amazon.com for allegedly brokering the sale of counterfeit watches. Macy*s department store was sued last year for selling Fossil® handbags allegedly incorporating counterfeit snaps. There also have been reports of advertisements posted by legitimate retailers for fake products, including an ad posted by Sears for what turned out to be a counterfeit Android®-powered iPhone®.

These examples demonstrate how easy it is for counterfeit products to penetrate even “legitimate” retail outlets and that patronizing such outlets is ultimately only as safe as the supply chain connecting products to consumers. Nor is the risk limited to counterfeit products infiltrating the supply chain. Even otherwise authentic products can take on harmful characteristics if they are diverted from authorized distribution channels into the “gray market.” Many regulated products are highly sensitive and can deviate from original specifications if subjected to extremes in temperature or humidity during shipment and storage, or altered during the repackaging process or maintained beyond their expiration dates. Products that escape into the “gray market” are often not properly controlled and are thus susceptible to corrupting environmental influences that can render the products adulterated or mislabeled and harmful to consumers.

Although manufacturers may not have a legal duty to “police their distributors” in order to protect consumers against counterfeits, they certainly have a strong economic interest to do what they can to mitigate counterfeiting risk, given that the unimpeded flow of counterfeits into the marketplace can erode consumer trust in a given brand, tarnish or even destroy a brand’s reputation, and inflict enormous financial harm on a brand owner. Similar risks apply to the widespread availability of diverted products that can be mishandled in ways that render them adulterated, mislabeled or harmful. Unlike with the part of a brand owner to police its own facilities and employees to prevent product diversion resulting in third party injury. Retail distributors of branded products similarly have a strong economic interest in ensuring that their suppliers are "clean" and that their inventories are not corrupted by counterfeit or diverted products.

What can be done? It is incumbent upon brand owners, as well as the authorized retailers carrying their products, to be more aggressive in securing their supply chains so that the worst-case scenario of a world without consumer trust in branded products never comes to pass. Every company, assisted as appropriate by outside counsel or other professionals, should perform both a "due diligence" review of third-party business partners and an "internal controls" review of their physical supply chain. Both types of reviews should be conducted periodically to ensure that information is current and keeps pace with changing business partner relationships.

A "due diligence" review of the suppliers, shippers, distributors, wholesalers, retailers and agents with whom you do business is needed to determine whether they pose unacceptable counterfeiting or diversion risks based on background, ownership, geography, business practices, legal history, media references, payment history or other relevant attributes. Such online investigation can be followed, to the extent practical and appropriate, by on-the-ground investigation, including site visits and on-site audits of business operations and records.

If appropriate effort and resources are directed to ensuring the security and integrity of products along the entire product supply chain, from the point of manufacture to the point of retail sale, then the risk of diverted and counterfeit products entering the legitimate supply chain can be greatly minimized, and the brand owner's most valuable asset – consumer trust – can be preserved well into the future. If supply chain security is neglected, however, then counterfeit and diverted merchandise will inevitably continue to seep into "legitimate" retail channels, steadily eroding consumer trust, brand owner profits and quality of life for everyone.

Remedial Guide to Size-up Potential Gaps

An "internal controls" review is needed to assist the company in evaluating whether there are loopholes or weaknesses in current procedures that must be remediated. A gap analysis should be developed comparing current supply chain procedures to best practices in a host of areas, including:

- Physical security and access control of facilities;
- Personnel security/employee screening;
- Training and education of employees on security policies;
- Transport and procedural security of goods through the supply chain;
- Documentation accuracy and information security;
- Incident reporting and investigation of missing/diverted products;
- Security requirements imposed on trading partners through contract or otherwise.

410 F. Supp. 2d 471 (S.D. West Virginia 2005).
Id. at 480.
Id. at 481. Id.
PR Newswire(fake handbags);
LA Times (fake art);
New York Times (fake art);
Response Magazine (fake home exercise kit).
San Francisco Chronicle (fake baby formula)
WWD (fake watches)
Caseclothesed (fake handbag snaps)
MaximumTech
ZDNet (fake iPhone running Android operating system)
410 F. Supp. 2d at 481.

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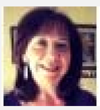

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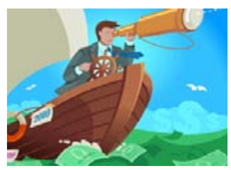

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