

Pharmaceutical Counterfeiting: The Effect of Technology, Regulation, and Legislation on Manufacturer Liability

By Caitlin C. Blanche



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In an age when the savvy consumer can run most errands without leaving the house, the question becomes, what price does one pay for the modern convenience of online shopping? Usually, it is a few extra dollars or a moderate shipping fee. With online pharmaceuticals, however, it could be much more serious because counterfeit pharmaceuticals have become big business in recent years. And it is not just online. What about those consumers getting their prescriptions the old-fashioned way by braving seemingly endless lines at the pharmacy? Well, as ever-more savvy counterfeiters develop new methods and channels for counterfeiting, even those consumers are at risk.

What you may not realize is that as more and more counterfeit drug operations hit the headlines, increased pressure falls on the pharmaceutical industry to prevent these acts. But intervening criminal acts preclude manufacturer liability, right? Technically, that is correct. However, the increasing foreseeability of counterfeiting and the broadened availability of anti-counterfeit technology threatens to obscure these once-clear rules. Although not likely to become the mass tort of choice in the next year, counterfeiting is something the pharmaceutical industry and its counsel should monitor. This article gives an overview of the counterfeit problem, the evolution of relevant technology, recent legislation that could affect manufacturers, and what

manufacturers should do to minimize exposure to potential lawsuits.

What Is a Counterfeit Drug?

According to the World Health Organization (WHO), a counterfeit medicine is “one which is deliberately and fraudulently mislabeled with respect to identity and/or source.” Counterfeiting encompasses both branded and generic products, and counterfeit products may have correct or wrong ingredients, no active ingredients at all, insufficient active ingredients, recycled expired medications, or products with fake packaging.¹

The anonymous and unregulated nature of the Internet provides a fertile breeding ground for counterfeiting prescription drugs. It is now the primary source for such criminal activity. The WHO estimates that over 50 percent of medicines purchased from rogue Internet sites that conceal their actual physical addresses are counterfeit in that most of these online pharmacies do not employ any licensed pharmacists.² In fact, a 2005 investigation by the Food and Drug Administration (FDA) of purported Canadian pharmacies revealed that 85 percent were actually located in 27 other countries, from India to Costa Rica to Vanuatu.³

Examples of Widespread Counterfeiting

In 2002, one-third to one-half of packets of Artesunate tablets, an anti-malarial drug, bought in Southeast Asia were fakes, containing no active ingredient.⁴ During a 1995 meningitis epidemic in Niger, more than 50,000 people were inoculated with fake vaccines, donated by a country that thought they were safe; as a result, 2,500 people died.⁵ Fake paracetamol cough syrup contaminated by diethylene glycol (a toxic antifreeze ingredient) caused 89 deaths in Haiti in

1995 and 30 infant deaths in India in 1998.⁶

Closer to home, in North America, the popular blood thinner Heparin was linked to a number of deaths due to allegedly counterfeit raw components from China that contained a dangerous ingredient that mimicked the real drug and fooled quality control tests. This Heparin mimic constituted as much as 20 percent of the product’s active ingredient.⁷

In 2003, the FDA recalled more than 18 million fake and repackaged Lipitor tablets. Those tablets, a combination of counterfeits and legitimate product of undetermined origin, were manufactured in Costa Rica from ingredients shipped from Hong Kong, repackaged by a Nebraska company, and distributed by a second company in Missouri. Typical of fake medicines, these tablets then passed through shell companies to create a false pedigree, making detection much more difficult.⁸

Development of Anti-Counterfeit Technology

Pharmaceutical manufacturers currently employ a variety of measures to fight counterfeiting. Common optically verifiable methods include safety seals, watermarks, bar codes, holograms, or patterns applied with special printing inks on the bottle or packaging of the pharmaceutical product itself. Tablets are sometimes made in unusual shapes that most counterfeiters cannot imitate. Some companies use electrostatic designs—engrained in the coating of the pill itself rather than applied to an already coated tablet—that are nearly impossible to replicate. Not every manufacturer, however, has the resources to incorporate these methods. Nor are watermarks, bar codes, holograms, and patterns applied with special printing inks immune to forgery. In addition, for

many of these methods to be effective, consumers must know what to look for—awareness that would require a concerted public health campaign.⁹

Apart from design, many manufacturers rely on pedigree to track their products. Pedigree refers to an audit trail, from the time of a drug's manufacture through the distribution system to pharmacies that track each successive sale, purchase, or trade, including the date of those transactions and the names and addresses of all parties. If done digitally, these are referred to as "electronic pedigrees."¹⁰ Although widely advocated by consumer advocates, pedigree programs are not foolproof. Pedigree paperwork can easily be forged and, like the counterfeits themselves, can create a false sense of security among pharmacists. The pedigree process is also labor intensive, requires significant documentation, and adds significant costs. Thus, many smaller wholesalers, facing a disproportionate burden, oppose any requirement that parties in a supply chain comply with a strict pedigree program. The 1987 Prescription Drug Marketing Act, mandating pedigrees in certain situations, has repeatedly been delayed by litigation brought by small wholesalers, and its enforcement was enjoined in 2006.¹¹

RFID Technology Is a Hot Topic

Radio frequency identification (RFID) tags have been extensively studied, debated, and sometimes implemented. The FDA views RFID as the most promising technology for electronic tracking and tracing across the supply chain.¹² This is an e-pedigree that stores and remotely retrieves data using devices called RFID tags or transponders. The tags are computer chips embedded in packaging or labeling that can be traced through each stage of distribution. Radio sensors at warehouses and pharmacies activate the chips, which are electronically scanned and stamped, automatically generating a shipping history and electronic pedigree.¹³

New section 505D of the Food, Drug and Cosmetic Act (FDCA) mandates development of standards for

identification, validation, authentication, tracking, and tracing of prescription drugs, with the FDA ultimately selecting a recommended method.¹⁴ The FDA recommends (but does not mandate) that the pharmaceutical industry adopt RFID technology to improve tracking and tracing as the beginning of an official e-pedigree program. The original 2007 implementation date has been extended to December 31, 2010, pending additional study of the technology.¹⁵

Although several major pharmaceutical companies have adopted RFID for various products, the technology has not reached full-scale implementation and,

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therefore, should not yet be considered an industry standard. A number of large manufacturers have actually publicly refused RFID, opposing its imposition for biologics because of unresolved concerns over effectiveness and feasibility.¹⁶

RFID opponents complain that (1) it adds significant cost to the product itself and requires special equipment to process the data being generated; (2) sophisticated counterfeiters can forge RFID tags; and (3) because RFID does not mark the product itself but marks the product packaging, it would be ineffective whenever drugs are repackaged, thus creating easily exploitable loopholes.¹⁷

The bottom line is that technology in this area is constantly advancing. Some companies have turned to state-of-the-art technology that detects suspected counterfeits through chemical fingerprinting¹⁸ analogous to matching DNA. One company markets technology capable of penetrating sealed bottles and reading the molecular fingerprint of the contents without destroying or altering

the product.¹⁹ Some manufacturers also hire web surveillance companies to track suspicious websites and detect fraudulent or counterfeit activity.²⁰

Counterfeit-Resistant Technology and Tort Liability

As more technologies become available and affordable, plaintiffs will contend that companies not employing technological protections—especially for drugs highly likely to be counterfeited—breach some duty to consumers.²¹ To date, attempts to create specified, mandated track-and-trace technology and a uniform pedigree system for high-risk pharmaceuticals have failed.²² As RFID grows ever closer to full-scale implementation, attorneys should be aware of any timelines for their clients' implementation. RFID is not new technology, but for pharmaceutical tracking, it is still being studied and tested in a controlled environment. Its adoption is not so wide as to preclude a state-of-the-art defense. But within the next year, as more and more companies switch to RFID as their primary track-and-trace system, the industry standard will change, making it a more technologically (and legally) feasible measure.²³

Legislation Aimed at Combating Pharmaceutical Counterfeiting

The past 20 years have seen various pieces of legislation affecting the pharmaceutical industry and pharmaceutical counterfeiting. More recently, a number of bills have targeted the importation and exportation of pharmaceuticals, which impose pedigree and track-and-trace requirements on manufacturers, distributors, and wholesalers.

The Counterfeit Drug Enforcement Act of 2005 and 2007, also known as Tim Fagan's law, was perhaps the most aggressive and industry-burdensome bill. First introduced in 2005, and then reintroduced in 2007, it was never passed. However, in light of growing support for this sort of aggressive legislation, its specifics are noteworthy. Among its features were a short mandatory reporting deadline on manufacturers that become aware of a potential

counterfeit incident and penalty provisions for manufacturers that have not implemented what the FDA determines to be feasible and necessary technology. Both aspects could create a tangible duty that plaintiffs could argue manufacturers have breached.

Another bill still pending—the Protect Consumers Act of 2009—would authorize the secretary of health and human services, upon finding reasonable probability that a drug intended for human use would cause serious health consequences, to issue cease-and-desist orders prohibiting either distribution of the drug or the drug's administration or prescription to patients; notify all persons affected by the risk; and order an immediate recall. Such orders would be

reviewable by an informal administrative hearing within 10 days, and a violation would be a prohibited act under the FDCA.²⁴

Legislation like Tim Fagan's law or the Protect Consumers Act would expand the concept of duty as courts interpret it. Although litigation so far has turned on findings that there was no case law, rule, or regulation creating a duty on the part of manufacturers to take any action to prevent counterfeit activity and no specific guidance about what action is appropriate following an incident, such legislation could change that. It would increase the burdens on the manufacturer and create arguments for plaintiffs to allege that manufacturers have breached a duty.

Can Manufacturers Be Held Liable?

Potentially, manufacturers could be held liable for harm caused by counterfeit drugs. Plaintiffs have tried to capitalize on some counterfeiting incidents. Although liability has not yet been imposed upon any manufacturer for injuries caused by counterfeit products, there are still caveats in the precedent and new opportunities for litigation as technology, supply chain management, and legislation are currently evolving.

Generally, plaintiffs claim manufacturers breached some duty to the consumer by failing to protect the consumer from foreseeable risk of counterfeiting through alleged misconduct or omissions, such as failing to make products and packaging tamperproof; failing to

Steps Manufacturers Can Take to Minimize Counterfeiting

Protect the Drug Supply Chain

First and foremost, a manufacturer should know the source of its raw materials and make regular inspections of its facilities in the United States and abroad. There should be internal audits at regular intervals and perhaps voluntarily business practices that ensure the legitimacy of their wholesalers. The Healthcare Distribution Management Association has issued Recommended Guidelines for Pharmaceutical Distribution System Integrity, which suggest performing due diligence of wholesalers, including an extensive information request before contracting; certification of the entity as an authorized distributor of record; a thorough background check to review criminal involvement, licensure status, state and federal inspections, credit history, financial status, and liability insurance; a site inspection; and contractual terms ensuring qualification and regulatory compliance and requiring regular review of compliance.ⁱ

Weigh the Balance of a Public Health Campaign

Educating consumers about the risks of counterfeits is a critical component of preventing their entry into the stream of commerce. There are trade-offs, because a strong public health campaign may cause some consumers to stop taking necessary medications after learning of the threat. There are also commercial and stigmatic risks. Beyond engaging in a cost-benefit analysis, manufacturers should also weigh potential liability for certain omissions, especially in the case of a frequently counterfeited drug or where the manufacturer knows of actual counterfeit activity involving one of its products.

Public health campaigns have involved magazine advertisements to warn pharmacists and customers; public warnings to hospitals, clinics, and patients; brochures about counterfeiting; and publications of details about counterfeiting incidents on webpages or

in press releases.ⁱⁱ In one case, a major manufacturer took the additional step of creating a graphic cinema advertisement featuring a man who receives supposed prescription drugs in the mail, pops a pill, begins to choke, and seconds later, pulls a rat out of his mouth.ⁱⁱⁱ

Be Wary of Insiders

In addition, internal regulation and surveillance are advisable. As with other kinds of theft, counterfeiters are not all strangers to the victim company. Rather, most counterfeit operations begin with an insider who, whether or not the brains behind the scheme, provides access to information about or to the targeted product. Pharmaceutical companies should routinely conduct background checks on their employees, including employees of contractors, and even cleaning personnel.

Use the MedWatch Form

The FDA encourages health professionals to use the MedWatch form as a mechanism to report suspect counterfeit drugs. To simplify the reporting of suspected counterfeits, the FDA changed MedWatch reporting instructions so that reporters will know how and when to report suspect counterfeits. The FDA has also updated the MedWatch website to add "suspect counterfeit" to the list of reportable product problems.

Endnotes

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ii. See Counterfeit and Importation, www.pfizer.com/products/counterfeit_and_importation/counterfeit_importation.jsp (last visited Mar. 3, 2009).

iii. Pfizer Ad Warns of Dangers of Fake Medicines, www.brandrepublic.com/Campaign/News/874161/New-ad-reveals-danger-buying-counterfeit-drugs/.

employ available anti-counterfeiting measures and technology; failing to warn pharmacies, doctors, and consumers of known counterfeit activity; and failing to supervise their supply chain properly by outsourcing critical manufacturing or failing to police distributors adequately.

Litigation Involving Counterfeit Drugs

The most notable and publicized case in this arena is *Fagan v. Amerisource-Bergen Corp.*, in which the defendant manufacturer learned of counterfeits of its drug being sold. It posted a letter on its website, notifying the public and provided guidance on ways to identify the counterfeits. Despite being warned by the pharmacy, the plaintiff took the counterfeit drug and sued the manufacturer. The court rejected purported manufacturer duties to (1) make products and packaging tamperproof; (2) continuously monitor products after they leave the manufacturer until purchased by the consumer; and (3) protect the public from foreseeable misuse of its products. The court held that a manufacturer of a product may not be held liable for negligence where, after a product leaves its possession and control, there is a subsequent modification that substantially alters the product and is the proximate cause of a plaintiff's injuries. The court went further to say that no packaging is completely tamperproof.²⁵

In *Ashworth v. Albers Medical, Inc.*, the court followed the holding in *Fagan*.²⁶ In *Ashworth*, the plaintiff alleged that a manufacturer should have designed a more counterfeit-resistant product and packaging; employed anti-counterfeiting measures identified in the 2004 FDA Report on Counterfeiting; and policed its supply chain to prevent introduction of counterfeits. The court viewed *Ashworth* as a tampering case and held that manufacturers do not have a duty to anticipate and frustrate criminal tampering. Even if the defendant had implemented the strictest available counterfeit measures, there was no evidence that the harm complained of would not have resulted. The court

found no common-law duty for manufacturers to ensure that products are counterfeit-proof. Nor did any statute, regulation, or rule place a duty on Pfizer to police its distributors; thus, Pfizer had no duty at common law to do so.

Similarly, in *Hayes v. Eli Lilly and Co., Bristol-Myers Squibb Co.*, 2005, a pharmacist received a lengthy prison sentence for diluting certain prescription drugs to a fraction of their stated potency. Plaintiffs sued both doctors and manufacturers, alleging negligent failure to stop the dilution schemes, as the pharmacist's sales records showed product sales exceeding the pharmacy's purchases. The companies argued that they had no duty to protect plaintiffs from an independent downstream seller's criminal acts. In that case, however, both manufacturers settled out of court with the plaintiffs.²⁷

There remains a gray area. No court has explicitly addressed the scope of a manufacturer's duty to warn the public about the danger once it is aware of specific counterfeit activity involving its products. The court in *Ashworth* noted that the complaint could broadly be read as alleging the manufacturer's negligent failure to warn the public and the plaintiff in a timely manner once it learned of counterfeit product in the marketplace and to issue a recall. The plaintiff, however, failed to defend that claim in opposition to a motion to dismiss; therefore, the court declined to address the issue further. The door thus remains slightly open for future claims.

In 2003, the Pharmaceutical Research and Manufacturers of America, the drug industry's primary trade association, announced its members' commitment to notify the FDA within five working days of determining that there is a reasonable basis to believe their product has been counterfeited. This voluntary reporting program began on May 1, 2003. No rule or regulation mandates compliance with this voluntary standard.²⁸

Last, there are exceptions to the general common-law rule that a person does not have a duty to protect others from the deliberate criminal conduct of third

parties. These are (1) where a person has a special relationship that gives rise to a duty to protect another person from intentional misconduct, or (2) where the person's affirmative actions or omissions have exposed another to a foreseeable high risk of harm from the intentional misconduct.²⁹ Plaintiffs can still argue that a significant act or omission by a manufacturer, such as inadequate warnings to the public after learning of counterfeiting activity involving its product or continuing to sell to someone implicated in such improper conduct, exposes the pharmaceutical manufacturer to liability. There are scores of attorney websites that advertise for clients claiming injury from counterfeit drugs. This is indicative that the litigation threat from counterfeiting remains real and is something the pharmaceutical industry and counsel should monitor.

Conclusion

Now, more than ever, attorneys should counsel clients about supply chain management, internal audits, the careful analysis and adoption of track-and-trace and anti-counterfeit technology, remedial measures, and monitoring of all relevant legislation introduced. Although courts have not yet imposed common-law liability for drug counterfeiting, there are a number of evolving variables in play, and plaintiffs could use any one of them to allege a new standard of care for manufacturers. ■

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Endnotes

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14. *See* 73 Fed. Reg. 78,371 (Dec. 22, 2008).

15. *See* Compliance Policy Guide; Radiofrequency Identification Feasibility Studies and Pilot Programs for Drugs; Notice to Extend Expiration Date, 73 Fed. Reg. 246 (Dec. 16, 2008).

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23. *See generally* FOOD AND DRUG ADMIN., COMBATING COUNTERFEIT DRUGS, *supra* note 12 (stating that "because the capabilities of counterfeiters continue to evolve rapidly, there is no single 'magic bullet' technology that provides any long-term assurance of drug security").

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