



New Angles for Potential Manufacturer Liability Stemming from Pharmaceutical Counterfeiting

How Industry Can Protect Brand and the Public Health at the Same Time

By Ellen L. Darling and Caitlin C. Blanche

The rise in the counterfeit drug market is of both domestic and international concern. And the concern is growing. A counterfeit drug may contain too much, too little, or the wrong and potentially toxic active ingredient. Or a label may misidentify a drug or its source. Because the pharmaceutical industry has shifted so much manufacturing and supply sourcing overseas, complete supply chains, from raw materials to finished products, have become more complex and less verifiable. Many of these complex supply chains spread across various countries and involve a web of handlers, suppliers, repackagers, and middlemen moving in and out of the shadows, making it easy for savvy counterfeiters to infiltrate supply chains at various weak points. And the anonymous and often unregulated nature of the Internet provides broad selling channels for these counterfeiting enterprises.

Pharmaceutical counterfeiting not only threatens public health, but it can harm both manufacturers' economic health and reputations. The time when manufacturers did not need to worry that such criminal acts would result in litigation against them because the acts were, in fact, intervening criminal acts, has faded. Several factors have left manufacturers more vulnerable than ever: increasing counterfeiting foreseeability, expanding anti-counterfeiting technology, and difficulty identifying the specific origin of contamination resulting in consumer injury due to blind spots in the supply chains. Drug manufacturers and their counsel should focus a large segment of their brand protection efforts on surveying and combating this criminal activity at every stage, both premarket and postmarket.

Could manufacturers bear liability for harm caused by counterfeit drugs? Potentially, yes. Although the plain-

tiffs' bar has not found much success litigating these cases to date, the door is now open further than ever. Generally speaking, those plaintiffs that have brought claims against drug manufacturers related to counterfeit incidents allege that manufacturers breached some duty to the consumer through omissions such as (1) failing to make products and packaging tamper-proof; (2) failing to employ available anti-counterfeiting measures and technology; (3) failing to warn pharmacies, doctors, and consumers of known counterfeit activity; and (4) failing to supervise their supply chains properly, either by outsourcing critical manufacturing or failing to adequately police distributors.

At first these lawsuits benefited manufacturers. *See, i.e., Fagan v. AmerisourceBergen Corp.*, 356 F. Supp. 2d 198 (E.D.N.Y. 2004); *Ashworth v. Albers Med., Inc.*, 410 F. Supp. 2d 471, 482 (S.D. W.Va. 2005) (holding that manufacturers do not have a duty to anticipate and frustrate criminal tampering). Subsequent cases over the next couple years fell in line. But things did not remain so black and white. First, no court has explicitly addressed the scope of a manufacturer's duty to warn the public about a danger *once it is aware* of specific counterfeit activity involving its products. The industry's awareness of the counterfeiting problem and the ability to uncover it earlier enhances the duty to react more vigilantly. Thus, shortcomings on this end could leave a manufacturer exposed without precedent to protect it.

Also, recent litigation stemming from contaminated lots of the anticoagulant heparin could reshape manufacturers' duties and liabilities. The first lawsuit that a court tried resulted in a plaintiff's verdict in the amount of \$625,000 this past June. *Janet Johansen v. Baxter Healthcare Corp., et al.*, CN 2009-L-011175 (Ill. Cir. Cook Co. June 2011). Hundreds of other heparin cases consolidated for pretrial proceedings under the multi-district litigation rules in the United States District Court for the Northern District of Ohio await trial decisions. The plaintiffs in these lawsuits allege that they suffered various reactions, including fatalities, to contaminated lots of heparin stemming from an incident several years ago.

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In late 2007, Baxter Healthcare Corporation, a heparin manufacturer, received a heightened number of adverse event reports of patients who experienced allergic-type reactions following administration of heparin. Baxter initiated voluntary recalls, suspended manufacturing, and launched a formal investigation. Scientists discovered that heparin's active pharmaceutical ingredient, API, which it obtained from Chinese suppliers, contained a contaminant—over-sulfated chondroitin sulfate, a synthetic compound with anticoagulant properties that mimics heparin—which, therefore, Baxter's standard quality tests did not detect. Baxter stated that an unidentified third party intentionally introduced the contaminant into its heparin during the early points of the product's supply chain in China. Baxter, the FDA, and Congress continue to investigate the incident but, to date, we don't know exactly who is responsible for replac-

ing the API with the contaminant or how and why the contamination took place. Consequently, the incident's qualification as "counterfeiting" is in dispute.

The lawsuits assert claims for strict product liability, negligence, and breach of express and implied warranties against Baxter and other companies. The plaintiffs claim, in part, that Baxter could have prevented the contamination by using better quality control processes and impurity identification procedures and more closely managing its supply chain.

Regardless of the outcome, we can take this lesson from the litigation: blind spots in a supply chain may make it impossible for a manufacturer to defend itself in a product liability action, even if the manufacturer acts appropriately once it learns of a problem and can trace alleged injuries to a specific contaminant. If a manufacturer's attorney cannot prove specific intervening criminal acts, there remains a

gray area, and the manufacturer may find itself liable for injuries linked to the adulterated product.

Now more than ever we should counsel our clients about (1) how to carefully restructure, monitor, and protect all levels of supply chains, including conducting internal audits, being wary of insiders, and conducting deeper background checks of employees; (2) weighing the balance of public health campaigns alerting the public to counterfeits; (3) using the MedWatch form as a mechanism to report suspected counterfeiting; and (4) keeping on top of the most up-to-date anti-counterfeiting technology available and legislation mandating its use. Although the plaintiffs' bar has not yet worked out a consistent formula for capitalizing on the counterfeiting trend, a number of evolving variables are in play, and the plaintiffs' bar could use any one of them to allege a new standard of care for manufacturers. 