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An Ounce Of Prevention: Dealing With The Threat Of Counterfeit Pharmaceuticals

Introduction

Unlike counterfeit handbags, watches, or movies that one can buy from a street vendor, counterfeit pharmaceuticals present a real and imminent public health risk. How to prevent counterfeit pharmaceuticals from entering the consumer supply chain has challenged the United States Food and Drug Administration (FDA) and other regulators since the late 1980s. FDA has not yet successfully implemented final regulatory safeguards in this arena, leading some drug manufacturers to delay implementation of anti-counterfeiting measures. Drug manufacturers are taking a considerable risk, however, by waiting for FDA to overcome the complexities of broad-based regulation.

First, when FDA issues final regulations, manufacturers must be ready to comply. Second, and more important, companies need safeguards against counterfeits in order to protect their businesses from profit loss, serious erosion of consumer confidence, and possible legal exposure. As regulators and courts delay, company exposure to each of these threats increases. Prudent manufacturers should make anti-counterfeit measures a current priority to prevent threats to their business from materializing into potentially irreparable harms.

This article outlines the regulatory landscape, identifies threats that counterfeit pharmaceuticals pose to the industry, and highlights proactive steps that drug manufacturers can, and should, take to protect themselves.

The Regulatory Landscape: Much Talk, But Little Action . . . Yet.

FDA has made it clear that protecting the consumer supply chain from counterfeit pharmaceuticals is a priority. One of this article's authors discussed FDA's most significant efforts in this regard in a 2004 article, *FDA Moves Forward on Fake Pharmaceuticals*.[1] That article highlighted FDA's then-recent creation of a Counterfeit Drug Task Force and outlined the various regulatory solutions the Task Force was considering. The Task Force Final Report stressed the "need for FDA and others to take action in multiple areas to create a com-

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1 Alan Minsk, *FDA Moves Forward on Fake Pharmaceuticals*, PHARMACEUTICAL FORMULATION & QUALITY, Dec.-Jan. 2004, at 26.

prehensive system of modern protections against counterfeit drugs."[2] The report acknowledged that, because counterfeiters are increasingly sophisticated, there is no "magic bullet" to protect the drug supply chain.[3] Accordingly, the report outlined a multi-pronged approach, which included: (1) implementation of new "track and trace" technologies such as radio frequency identification (RFID) that would aid in the creation of reliable drug pedigrees; (2) adoption and enforcement of tougher state licensure rules and regulations for wholesale distributors; (3) increased criminal penalties to deter counterfeiting; (4) adoption of secure business practices by all companies in the supply chain; (5) development of reporting and rapid response systems; and (6) education of consumers and the public about the risks of counterfeit drugs.[4]

The 2004 report provided an optimistic roadmap. Even though it did not create binding regulations, the report predicted that supply chain participants would voluntarily adopt RFID or similar track and trace technologies by 2007, allowing them to create electronic "pedigrees" for prescription drugs.[5] FDA defines a pedigree as "a record documenting that the drug was manufactured and distributed under secure conditions." It typically involves an identifying statement that documents each prior sale, purchase or trade of the medicine. FDA believed that widespread adoption of track and trace technology would enable companies to "meet and surpass" the requirements of the Prescription Drug Marketing Act of (PDMA), which requires certain drug distributors to provide pedigrees for the drugs they sell. [6] Following the 2004 report, FDA delayed the effective date of certain final regulations implementing PDMA. FDA expected that the delay would enable companies to rapidly adopt track and trace technologies.[7] The delayed regulations, 21 C.F.R. Sections 203.3(u) and 203.5, defined which supply chain participants would be responsible for providing a pedigree, what the pedigree would have to include, and how far back the pedigree would have to trace the drugs.[8]

In June 2006, FDA announced that it would no longer delay implementation of Sections 203.3(u) and 203.5, because it had become apparent that the industry would not fully implement track and trace technology by 2007.[9] The electronic pedigree system had not emerged to "meet and surpass" the requirements of PDMA as FDA had initially envisioned in 2004. Sections 203.3(u) and 203.5 are still not in effect, because wholesale distributors brought suit to enjoin FDA from implementation. The plaintiff distributors obtained a preliminary injunction against FDA while they argue the merits of their case.[10]

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2 COUNTERFEIT DRUG TASK FORCE, COMBATING COUNTERFEIT DRUGS: A REPORT OF THE FOOD AND DRUG ADMINISTRATION, at i (Feb. 18, 2004) [hereinafter COUNTERFEIT DRUG TASK FORCE REPORT].
3 *Id.*
4 *Id.* at i-iv.
5 *Id.* at 15-16.
6 COUNTERFEIT DRUG TASK FORCE REPORT, *supra* note 2, at 15-16; The Prescription Drug Marketing Act of 1987, 21 U.S.C. §§ 331, 333, 353, 381 (as modified by the Prescription Drug Amendments of 1992).
7 71 Fed. Reg. 34249-34251 (June 14, 2006).
8 *See* 21 C.F.R. § 203.3(u) (defining what constitutes an "ongoing relationship" under PDMA sufficient to qualify a distributor as an authorized distributor of record); 21 C.F.R. § 203.5 (stating the fields of information that must be included in a drug pedigree and specifying that the information must be traceable back to the first sale by the manufacturer).
9 71 Fed. Reg. 34249-34251 (June 14, 2006).
10 *RxUSA Wholesale, Inc. v. FDA,* 467 F. Supp. 2d 285 (E.D.N.Y. 2006) (preliminary injunction *aff'd,* No. 07-0453-cv, slip op. (2d Cir. July 10, 2008)).

Numerous states have begun to consider or have passed track and trace legislation that would enhance the requirements of PDMA, but this legislation, much like the FDA regulations, has been slow to come to fruition.[11] In California, for example, the legislature has repeatedly delayed the implementation of state electronic pedigree rules.[12] The most recent bill in California would allow manufacturers to select twenty percent of their product line to meet electronic pedigree requirements by 2011, fifty percent by 2013, and one-hundred percent by 2015.[13]

Drug companies should understand that the current regulatory situation is merely a delay and not a retreat from eventual rules governing drug pedigrees. Companies should see the current delay as an opportunity to have a proactive hand in shaping future regulations that protect them and their consumers and are also financially and logistically feasible. Counterfeit drugs pose significant threats, both to consumer safety and drug company bottom lines that merit proactive response from all stakeholders. The following section explores some of these threats in more detail.

Potential Threats to Pharmaceutical Companies

In addition to the regulatory issues to consider with counterfeiting, there are also other issues. Counterfeiters are able to offer a lower price point than the manufacturer and, therefore, pose an unfair competitive threat that can erode pharmaceutical company profits. Counterfeiting and other forms of intellectual property theft cost American businesses at least $250 billion annually and counterfeit drugs worldwide cost pharmaceutical companies as much as $46 billion annually.[14] Moreover, industry metrics suggest that the counterfeit threat to profits is growing steadily. The government projects that United States spending on pharmaceuticals will surpass $247 billion in 2008 and, as consumer spending increases, so does the incentive for counterfeiters to encroach upon the legitimate market.[15] In recent years, FDA has reported an increase in criminal investigations of counterfeiters in the domestic market – a fact which may suggest "an increase in the prevalence of fake products in the United States."[16]

Pharmaceutical companies also risk serious loss of consumer confidence as counterfeits become more prevalent. Increasingly, counterfeiters are dealing in drugs that are vital to consumer health, such as drugs for hypertension and high cholesterol.[17] A counterfeit scare involving such vital drugs could substantially

11 States that are considering or have passed pedigree legislation include Colorado, Florida, Georgia, Idaho, Kentucky, Maryland, Massachusetts, North Dakota, South Dakota, Utah, Wisconsin, and Wyoming. National Conference of State Legislatures, 2008 Prescription Drug State Legislation, http://www.ncsl.org/programs/health/drugbill08.htm [hereinafter 2008 State Drug Legislation].
12 *California E-Pedigree Phase-In Bill Moving Through State Legislature,* THE PINK SHEET, June 30, 2008, at 25.
13 S.B. 1307; *Id.*
14 Candace S. Friel, *The High Costs of Global Intellectual Property Theft: An Analysis of Current Trends, The TRIPS Agreement, and Future Approaches to Combat the Problem,* 7 WAKE FOREST INTELLECTUAL PROP. L.J. 209, 215, 220 (2007).
15 2008 State Drug Legislation, *supra* note 12.
16 Friel, *supra* note 15, at 219-220.
17 *Id*. at 220.

reduce consumer confidence in certain drug companies and brands of drugs. Companies that make large investments in developing their good will with consumers and establishing a trademarked brand name and image that inspires confidence must be proactive in protecting this substantial investment. Once a counterfeit product has entered the market, it can adversely affect good will and infringe upon trademarks but the company will not become aware of the problem until the damage is done and potentially irreversible.[18]

For example, Pfizer was not aware that counterfeits of its cholesterol drug Lipitor had infiltrated the United States market until consumers began to complain. More than eighteen million fake Lipitor tablets were recalled following the consumer complaints and the company estimates that counterfeits had reached 600,000 consumers in fifteen states.[19] The company estimates that the total cost of the recall was in the tens of millions of dollars. Pfizer now includes a case study about the counterfeit Lipitor problem in a special section of its website that addresses current issues related to counterfeit drugs.[20] Pfizer developed and posted this case study of its own initiative, indicating that the company sees the Lipitor counterfeit case as an important lesson learned. Today, Pfizer invests time and money into distributor auditing initiatives that aim to prevent counterfeits from causing additional harms to the company's reputation, consumer base, and bottom line.

In addition, pharmaceutical companies may face product liability claims as more consumers suffer harm from faulty counterfeits. The line between an actual counterfeiter and innocent companies further down the supply chain can be imprecise. This is because "counterfeiters are clever, good at covering their tracks, and often appear to be innocent."[21] Because of this confusion, product liability plaintiffs may not have to prove intent to counterfeit to prevail against defendant companies. Rather, plaintiffs might try to make their case by showing "willful blindness" on the part of the company.[22] The willful blindness standard is problematic from the perspective of drug manufacturers and other legitimate supply chain participants, because it holds companies liable for harms that fake drugs cause, even if the company did not intentionally or actively place the counterfeits into the supply chain. In a case involving retail sales of counterfeit Tommy Hilfiger shirts, the Court held the retail defendant liable because the defendant had reason to suspect that the shirts were counterfeit yet failed to take proactive steps to assuage any suspicions.[23]

Drug manufacturers and legitimate distributors must be proactive in protecting the supply chain in order to minimize the risk of similar forms of liability for counterfeit pharmaceuticals. Legal scholars and consumer activists have begun to advocate theories of liability that would extend the willful blindness rationale in the Hilfiger case to cases involving pharmaceutical manufacturers. One commentator posits

18 Bradley J. Olson et al, *The 10 Things Every Practitioner Should Know about Anti-Counterfeiting and Anti-Piracy Protection*, 7 J. High Tech. L. 106, 111 (2007).
19 Pfizer, Inc., Case Study: Lipitor U.S. Recall, http://media.pfizer.com/files/products/LipitorUSRecall.pdf [hereinafter Lipitor Case Study].
20 Lipitor Case Study, *supra* note 20.
21 Olson et al, *supra* note 19, at 118.
22 *Id.*
23 *Tommy Hilfiger Licensing, Inc. v. Goody's Family Clothing, Inc.*, No. 1:00-CV-1934-BBM, 2003 WL 22331254 (N.D. Ga. May 9, 2003).

that counterfeit activities "are not 'beyond the control' of the manufacturers" because "they have chosen the group of distributors to which they sell" and are therefore "responsible for…the overly complex …web" of drug distribution.[24] Drug companies may disagree with the assertion that they "[c]learly…determine how…medicine is distributed," but they should be aware that legal theorists are making this assertion and that it bolsters potential product liability claims.

If a drug company has any reason to suspect potential counterfeiting of one of its products, it should engage FDA and other government officials. The government can prosecute counterfeiters under a variety of criminal statutes that come with tough sanctions and may deter future counterfeiters. The United States Court of Appeals for the Fifth Circuit affirmed a series of criminal convictions in 2006 against online pharmacy owners who had dispensed controlled substances to consumers without valid prescriptions.[25] The convictions in that case included: conspiracy to distribute a controlled substance in violation of 21 U.S.C. § 846; dispensing a controlled substance not in the usual course of professional practice in violation of 21 U.S.C. § 841(a)(1); and engaging in continuing criminal enterprise (CCE) in violation if 21 U.S.C. § 848.[26] The sanctions associated with each of these convictions are substantial. A CCE conviction, for example, carries a mandatory sentence of several years in jail. See 21 U.S.C. § 848(a) Government criminal investigations and enforcement are powerful tools within the pharmaceutical company's arsenal against counterfeits.

Preventative Measures: Proactive Coordination both Internally and Externally

Pharmaceutical companies should be proactive today to counteract future problems stemming from counterfeit products. This entails becoming actively involved in the regulatory process and developing industry-wide controls. No single department within a company can do this successfully on its own and no single company can do this without the partnership of other companies within the industry.

Proactive companies can learn from the travails of federal regulators who have sought to address the counterfeit problem. A principal reason for the delay in final pedigree regulations is that counterfeit pharmaceuticals exist in a complex supply chain environment and the counterfeiters themselves adopt increasingly advanced technologies to circumvent safeguards. Any flaw within the complex supply cha+in can allow counterfeits to slip into the market. The absence of a magic bullet technology or a single party that can take full responsibility for preventing counterfeiting has made it difficult for regulators to settle on a final protocol that will work well and satisfy all stakeholders. Accordingly, FDA has advocated collaboration across agencies with different strengths regarding regulation and enforcement. Pharmaceutical companies can, and should, adopt a similar collaborative strategy both at the internal and external levels.

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24 Stephanie Feldman Aleong, *Green Medicine: Using Lessons from Tort Law and Environmental Law to Hold Pharmaceutical Manufacturers and Authorized Distributors Liable for Injuries Cause by Counterfeit Drugs*, 69 U. PITT. L. REV. 245, 251-52 (2007).
25 *United States v. Fuchs,* 467 F.3d 889 (5th Cir. 2006).
26 *Id.* at 898-99.

At the internal level, the counterfeit issue poses problems for almost every function of the drug business. Brand managers and product line managers should be concerned about potential trademark infringement, loss of good will, and lost profits. Logistical specialists, operations managers, and quality control departments need to design protocols and adapt new technologies that will enhance controls. Legal and regulatory affairs departments should be prepared to manage whatever final regulations evolve in the near future and should also act now to ensure that their companies can respond effectively once the regulations are finalized. Even at the research and development level, companies have an incentive to encourage proactive thinking about ways to develop products that are difficult to tamper with or replicate. Finally, senior management must demonstrate its commitment by expending the necessary time and resources to allow these applicable departments to implement a strategy. The prevention of counterfeiting essentially touches every function of the business and accordingly requires executive level coordination to ensure that each business function works with the others to devise optimal solutions. Such actions make both good legal and financial sense.

At the external level, companies must ensure that the stream of commerce in which they participate is as secure as possible. Careful selection of distribution partners and quality control coordination by contract are necessary but not sufficient steps to managing the problem. Companies have to develop regular monitoring procedures to ensure on an ongoing basis that both internal departments and external supply-chain partners are adhering to proper protective protocol. While very few market participants might actually intend to contaminate the market with counterfeits, all market participants are at risk for acting negligently because the optimal protective protocols and technologies are constantly evolving. Even a well-intentioned manufacturer or distributor might be liable if controls are not sufficient to overcome a potential claim of "willful blindness." Companies can manage this complicated problem through a mutual support system that involves regular monitoring and broad-based coordination internally and with industry partners. Companies can pay now or they can pay later.