

THE CROSSROADS OF PHARMACEUTICAL PEDIGREE AND PRODUCT LIABILITY LITIGATION

By Paul J. Maloney

Pharmaceuticals are high value items that pass through numerous hands before reaching the consumer. This creates significant opportunity for counterfeiting, and associated profit on the part of those wrongdoers. Counterfeiters put innocent lives at risk, compromise product integrity, and undermine the faith in the pharmaceutical delivery system in this country. The FDA has been stymied in its efforts to implement a pedigree system for uniform delivery of drugs both by industry resistance and court intervention. As such, pedigree legislation rests, by default, with the individual states for enforcement of inconsistent pedigree laws.

The annual global market for pharmaceuticals is estimated at \$500 billion. The World Health Organization (“WHO”) reported in 2006 that the counterfeit drug industry worldwide had revenues of over \$40 billion. The same report also referenced that counterfeit drug sales will likely reach \$75 billion globally by 2010.

Despite having a well developed—albeit complex—drug distribution program, the United States is not immune to counterfeit drugs. Best estimates are that 1% of all prescription drugs in this country are counterfeit. A recent PhARMA press release estimates that the scope of all counterfeit business—not just drugs—costs the US economy between \$200 billion and \$250 billion per year, and is responsible for the loss of more than 750,000 American jobs.

Not a day passes without there being some article in the news concerning counterfeits in general, and counterfeit and/or adulterated drugs in particular. www.safemedicines.org maintains a running list of reference articles. *The Washington Post* ran an article on February 7, 2008 captioned “Safety of Drug Imports Questioned: Some In Congress Want FDA to Expand Overseas Inspections.” The article referenced a letter written by Senator Grassley of Iowa to the FDA on February 1, 2008 concerning the number of inspections in China that dropped from 18 in 2004 to 11 in 2007. The article noted that China is believed to have hundreds, if not thousands, of plants that make ingredients for drugs headed to the United States. The FDA responded that it cost the agency \$6.2 million in 2007 to pay for 300 foreign drug inspections. The Bush administration was pushing for a 5.7% increase.

Twelve days later, *The Washington Post* ran an article on page 1 captioned “FDA Says It Approved the Wrong Drug Plant: Heparin Probe Sends Inspectors to China.” The Chinese facility that produced the active ingredient for the blood-thinner Heparin was never inspected by the FDA because the agency confused its name with another. The article pointed out that there have been 350 adverse reactions to the Heparin reported to the FDA since the end of 2007, and four patients who took the drug died. As of April 8, 2008, the number of reported deaths is 62.

On May 1, 2007, the FDA released an alert to consumers about counterfeit drugs from multiple internet sellers. Six weeks later, counterfeit drugs purchased over the internet were blamed for the death of a woman in Vancouver, Canada. It was widely reported that this was the first clear cut case of death from counterfeit drugs bought on the internet, but as the Regional Coroner for Vancouver Island stated, “It likely won’t be the last.” The pills taken by decedent had 15 times the amount of aluminum that would be considered fatal.

On January 31, 2008, *The New York Times* reported that nearly 200 Chinese cancer patients were paralyzed or otherwise harmed last summer by contaminated leukemia drugs. The same Chinese drug maker is the sole supplier to the United States for the abortion pill known as RU-486. Approximately one-half of those injected with the contaminated leukemia drug could not walk as a result of the injections. The same article referenced 18 Chinese who died in 2006 after taking an intravenous drug used to treat liver disease, which was laced with diethylene glycol, a toxic chemical used in some antifreeze. Also in 2006, at least fourteen Chinese died after taking a Chinese antibiotic that was not properly sterilized during production.

Counterfeit Crime Wave

The market for counterfeit drugs in this country has been compared to organized crime in its level of sophistication. Counterfeiters pocketed \$28 million in a single transaction for diluted Epogen. As many as 25,000 cancer patients may have received sub-potent medicine that was one-twentieth (1/20th) the prescribed strength when Procrit was re-labeled by U.S. counterfeiters. The counterfeiters earned approximately \$46 million. Criminal prosecutions are few and far between. One problem is that the evidence is destroyed by patient use. Another is that the effects of a counterfeit pharmaceutical are often attributed to an underlying disease. If a patient dies, the cause of death will typically be related to the underlying disease process, and not as a result of a counterfeit drug. The FDA and U.S. Attorney's Office are generally understaffed and unwilling to tackle the complexities of the counterfeit drug business in this country. This results in a high profit, low risk trade off for the criminal element, which will likely continue.

Nevertheless, there have been some high profile prosecutions. Julio Cesar Cruz received a thirteen years six month sentence without the possibility of parole for masterminding the 2003 Lipitor scam. He had previously been convicted of distribution of cocaine. In addition to his sentence, he was ordered for forfeit more than \$2 million in profits for selling counterfeit drugs and participating in a conspiracy to purchase and sell counterfeit, misbranded and illegally imported drugs. Numerous co-conspirators received sentences as well, to include one who supervised the importation of counterfeit prescription drugs into the United States who received a nine year and six month term without parole.

Another high profile case involved Marc Anthony Kolowich, who was sentenced to 51 months in jail in a case prosecuted by the San Diego United States Attorney. Kolowich operated an internet pharmacy website at www.worldExpressrx.com from which customers could order prescriptions without having a prior prescription. Customers were to fill out a health questionnaire and pay a \$35 fee for a doctor's consultation, but there was no doctor involved. Kolowich received a 51-month jail sentence and forfeited \$3 million in assets. Many of his co-conspirators plead guilty, and received sentences, most of which amounted to a slap on the wrist.

The case of Michael Carlow has been well documented. He was the subject of a book by Catherine Eban, *Dangerous Doses: How Counterfeiters are Contaminating America's Drug Supply*. Carlow's scheme included Medicaid fraud, counterfeit re-labeling, and diversions through offshore companies. At his zenith, Carlow operated more than two dozen front companies in a half dozen states, and generated \$3 million per month. He plead guilty in November 2006 to charges of selling \$42 million in counterfeit drugs to one distributor.

Intersection of Pharmaceutical Pedigree and Product Liability Litigation

I have now touched upon the scope of the counterfeit drug problem in this country. Where does this leave manufacturers, distributors, and pharmacies when a product liability lawsuit is filed on the basis of counterfeit drugs? The leading case on this topic is *Fagan v. AmerisourceBergen Corp., et al.* (hereinafter “ABC”).

Facts: 18 year old Timothy Fagan filed suit in the Eastern District of New York alleging that following a liver transplant on February 15, 2002, he was provided—and used—two months worth of counterfeit Epogen. His lawsuit was filed against ABC, Amgen, CVS Corporation, and Procure Pharmacy (a subsidiary of CVS).

The facts are straightforward. CVS delivered three prescriptions to Mr. Fagan from two different lot numbers from March 20th to May 20, 2002. Six days after Amgen posted a warning on its website of the potential for counterfeit Epogen, CVS called plaintiff to advise him of the problem. The Epogen delivered was 1/20th the strength set forth on the label. Fagan claimed medical damages to include worsening anemia, excruciating pain from the below strength injections, and delayed recovery from the liver transplant. The lawsuit included the usual claims for negligence, breach of implied and express warranty, fraudulent misrepresentations, *etc.*

Each of the parties filed a Motion to Dismiss the Complaint at the outset of the litigation.

Amgen: The manufacturer moved to dismiss claiming that it had no duty to: (1) make its product tamper resistant; (2) continuously monitor its products from the time it left its control until the time purchased by the consumer; and (3) protect the public from criminal misuse, even if foreseeable. The court agreed with these arguments, and dismissed the claim. In finding that Amgen owed no duty to Fagan under the circumstances, the court established favorable precedent for manufacturers in similar counterfeit cases. As the court noted:

“Plaintiff cannot establish that it was feasible for Amgen to design the Epogen in a safer manner. Even if Amgen was aware of the diversion and counterfeiting of prescription drugs, and that its packaging could be violated by a counterfeiter, no packaging is completely tamper-proof.”

“...a manufacturer does not have a duty to anticipate and prevent criminal conduct by third parties, or to design its product in such a way as to anticipate and frustrate criminal tampering.”

ABC: Similar to Amgen, ABC argued that it owed no duty to plaintiff, and even if it owed a duty, the criminal conduct of others was the proximate cause of damage to Fagan. The court was not as receptive to ABC’s arguments as it was to those of Amgen. Specifically, the court found that there was a “special relationship” between the distributor and the plaintiff since the distributor was in the best position to protect Fagan from harm. In finding that ABC owed a duty, the court noted:

“...ABC was in the best position to prevent the harm alleged by modifying its practices so as to avoid purchasing its drugs from the ‘gray market.’ Accordingly, plaintiff’s allegations sufficiently raise factual questions as to whether ABC owed him a duty of care.”

The court also rejected ABC's claim that an intervening criminal act by a third-party cut off its liability in noting that:

"...since plaintiff has alleged that ABC knew that its distribution practices helped to foster the "gray market," it was reasonably foreseeable that by continuing to do so, a person would be able to counterfeit or misbrand prescription drugs and deliver such drugs to retailers, who would then pass them along to unwary consumers."

Pharmacy: CVS also filed a Motion to Dismiss. It contended that: (1) it did not knowingly dispense a drug that was inferior or defective; and (2) it did not have a duty to warn customers of potential criminal misuse of a medication. The court again disagreed, and at least at the Motion to Dismiss stage of the litigation found that there were factual issues to include:

"...potentially negligent conduct on the part of CVS ProCare, including, *inter alia*, its failure to inspect the label of the medication purchased from ABC, which was purportedly defective on its face."

It should be noted under New York law of this case a pharmacist has an obligation "to exercise the highest practicable degree of prudence, thoughtfulness, and vigilance, and the most exact and reliable safeguards consistent with the reasonable conduct of business." In reaching its decision, the court also made reference to an allegation in the Complaint that CVS knew of the counterfeiting and diversion of prescription drugs since 1988, and the fact that some of its drugs may have been purchased on the "gray market" was sufficient to preclude dismissal of the negligence claim at the outset of the case.

As a result of the initial rulings, the entire claim was dismissed as to Amgen, negligence claims were allowed to go forward against ABC and CVS, and the implied warranty of merchantability claim allowed to go forward as to CVS. In applying New York law, the court in *Fagan* held the distributor and dispenser to a higher standard than that of the manufacturer. The court found it significant that the distributor had knowledge of the "gray market" and questionable practices related thereto. The distributor was also the first in the line of distribution to be able to pick up on the counterfeit drug, and failed to do so. The finding against the pharmacist appears harsh on its face, but New York has no equivalent statute to the "sealed container" defense available in many states. The court put both CVS and ABC in a position to, in essence, prove that they did not know of a "gray market" for Epogen—something difficult to do.

Lipitor Recall

The Lipitor scam from 2003 forms the factual backdrop for two additional counterfeit drug cases. The following facts are gleaned from *Arons v. Rite Aid Corporation*, 2005 WL 975462 (NJ Super. L.) (March 23, 2005) and *Ashworth v. Albers Medical, Inc., et al.*, 395 F. Supp. 2d 395 (2005). Lipitor, the best selling prescription drug in the world, is used to lower cholesterol. It is exclusively manufactured by Pfizer Ireland Pharmaceuticals, and distributed by Pfizer, Inc. in the United States. In late-2002, Albers Medical Distributors, a national distributor for prescription and over-the-counter pharmaceutical products, purchased hundreds of bottles containing 5000 tablets each represented to be 10 mg of Lipitor. Albers also acquired smaller quantities of bottles containing tablets represented to be 20 mg of Lipitor. Albers obtained

written pedigree information, which turned out to be counterfeit. Numerous individuals with experience in the wholesale drug industry reviewed the pedigree data during the time the tablets navigated through the supply chain. None picked up the counterfeit paperwork. The pedigree data showed that 774,180 of the 10 mg tablets had been bought and sold by six different entities in Puerto Rico, Tennessee, Maryland, Missouri, and Illinois within a nine-day period in early-2003.

When Albers bought the tablets, it contracted with MedPro, Inc., a pharmaceutical repackaging specialist in Nebraska to repackage the tablets from 5000 tablet bottles into 90-tablet packages. As the scam unfolded, Med-Pro declared bankruptcy. The aforementioned Mr. Cruz and Mr. Carlow were both involved in the scam. Mr. Albers was indicted as well.

In November 2002, Albers began to sell a substantial quantity of 90-tablet packages represented to be 10 mg Lipitor and 20 mg Lipitor to H.D. Smith Wholesale Drug Company. H.D. Smith, in turn, sold substantial quantities to Rite Aid Corporation in March and April 2003, and smaller quantities to Americare Pharmacy in February 2003. As of February 2003, Rite Aid operated 3,356 stores throughout 28 states and the District of Columbia. Between April 3, 2003 and June 1, 2003, Rite Aid pharmacies dispensed approximately 16,600 tablets represented to be Lipitor, a portion of which it had purchased from H.D. Smith.

Ashworth v. Albers

In April and May 2003, plaintiff, Tammy Ashworth, purchased 30 tablets purporting to be Lipitor from a pharmacy in Big Chimney, West Virginia operated by Rite Aid of West Virginia. On the day after Ms. Ashworth made her second purchase, the FDA announced that Albers had agreed to a voluntary recall of three lots of 90-tablet bottles of 10 mg Lipitor repackaged by Medpro. By mid-July, based on additional FDA testing, approximately 200,000 bottles had been recalled.

Rite Aid notified its customers, including Ms. Ashworth, of the potential problem on June 9, 2003. The notice indicated it was impossible to tell through inspection whether the Lipitor she received was safe for use, so it requested that the tablets be returned to Rite Aid for replacement. Only after receiving the notification from Rite Aid, Ms. Ashworth notified her physician that she had experienced dizziness, sluggishness, and chest pains from April 24th to June 9, 2003. Her treating physician confirmed “dangerously high” levels of triglycerides, and admitted her to the hospital for treatment.

Ms. Ashworth proceeded to file a ten-count complaint alleging the usual misdeeds by the corporate defendants. She chose to sue Pfizer, Albers, Medpro, H.D. Smith and Rite Aid. The reported decision from the United States District Court in West Virginia only dealt with Rite Aid’s Motion to Dismiss and several other procedural issues. Rite Aid presented three arguments to the court: (1) it was entitled to a statutory sealed container defense; (2) it was entitled to a learned intermediary defense; and (3) there was no indication that Rite Aid had any knowledge that the Lipitor was counterfeit or had knowledge of a counterfeit operation.

The court agreed, and dismissed Rite Aid. The court found that there were:

“No allegations that Rite Aid knew or should have known that the Lipitor sold to plaintiff was counterfeit, whether by observing the tablets or the bottles in which the tablets came.”

The court in *Ashworth* distinguished the *Fagan* case noting that New York had no statutory scheme for the sealed container defense. It also pointed out that Rite Aid had no knowledge of prior counterfeiting practices as had been alleged in the *Fagan* case.

Typically, products liability cases trace back to the manufacturer in an upward stream from the seller. The *Fagan* court effectively eliminates the manufacturer, at least under New York law, for counterfeit schemes first undertaken by distributors. The *Ashworth* court, in construing West Virginia law, eliminates the ultimate drug dispenser from liability so long as there is not prior knowledge of counterfeit activity. Both cases tend to focus the inquiry on the distributor closest to the party that engineered the counterfeit scheme in the first instance.

Arons v. Rite Aid Corporation

The *Arons* case involved the same Lipitor scheme as the *Ashworth* case. Here, three plaintiffs in New Jersey filed a lawsuit against a host of defendants alleged to have been involved in the distribution of the counterfeit Lipitor. In this case, none of the three plaintiffs were alleged to have had adverse health effects, and one of the plaintiff’s cholesterol levels had even improved during the time he had taken potentially counterfeit Lipitor. In a well-reasoned opinion, the trial court refused to certify a class action suit as requested by plaintiffs. This was a resounding win for defendants in counterfeit drug cases, and will serve as a road map for future efforts to defeat similar class certification requests. In particular, the court found that:

“It is entirely unclear whether plaintiffs may have been among the unlucky ones who acquired tablets that are actually bogus. To extrapolate from the voluntary recall episode that plaintiffs likely were so unlucky creates impermissible speculation and conjecture.”

In part, the court justified the denial of the class certification as follows:

“...it is impossible to know with any certainty exactly what each purchaser took home in the tablets acquired from the pharmacies. The individual contents of the bottles sold at retail remain unknown. Many purchasers consumed their tablets. Some returned the leftovers to Rite Aid and Americare. Some retained their tablets. Just because the universe of tablets sold in the Spring of 2003 was the subject of a voluntary recall does not circumstantially demonstrate a breach of warranty.”

In addition to denying class certification, the court dismissed consumer fraud claims, but did allow certain warranty claims to go forward.

The *Fagan*, *Ashworth*, and *Arons* cases are the leading cases involving the intersection of counterfeit drugs and product liability claims. These cases point out the problems that plaintiffs will have in prevailing in a counterfeit drug case. Problems include: (1) preservation of the

evidence; (2) proof that a counterfeit drug actually caused injury; (3) proof that any of the defendants had actual knowledge of the counterfeit activity; and (4) to the extent that class certification is denied, such cases may be prohibitively expensive for an individual plaintiff absent severe personal injury. These cases bode well for the defense of product liability claims arising out of counterfeit drug sales.