GREEN MEDICINE: USING LESSONS FROM TORT LAW AND ENVIRONMENTAL LAW TO HOLD PHARMACEUTICAL MANUFACTURERS AND AUTHORIZED DISTRIBUTORS LIABLE FOR INJURIES CAUSED BY COUNTERFEIT DRUGS

Stephanie Feldman Aleong

Available at: https://works.bepress.com/stephanie_aleong/1/
GREEN MEDICINE: USING LESSONS FROM TORT LAW AND ENVIRONMENTAL LAW TO HOLD PHARMACEUTICAL MANUFACTURERS AND AUTHORIZED DISTRIBUTORS LIABLE FOR INJURIES CAUSED BY COUNTERFEIT DRUGS

BY STEPHANIE FELDMAN ALEONG

I. Introduction

The majority of the American public would be astonished by the frequency with which counterfeit prescription drugs appear on reputable drug store shelves. In 2004, the Food and Drug Administration noted that those who counterfeit prescription drugs “deny ill patients the therapies that can alleviate suffering and save lives.” In 2006, the World Health Organization estimated that a $30 billion market in fake drugs exists. Although the FDA has also tried to characterize the incidence of counterfeit medications in the U.S. prescription drug marketplace as “rare,” numerous instances of counterfeit drugs

---

1 Stephanie Feldman Aleong is an Assistant Professor of Law and Director of the Masters of Science in Health Law Program at Nova Southeastern University, Shepard Broad Law Center, in Ft. Lauderdale, Florida. Prior to becoming an academic, Professor Aleong was Florida’s Health Care Fraud Priority Leader in the Office of the Statewide Prosecutor. She also serves on the Advisory Board for Secure Symbology, Inc., a technology company aimed at bar-coding many products to enhance inventory control and safety. Professor Aleong first presented the concept of this article at the American Society of Law, Medicine and Ethics’ 30th Annual Health Law Professors’ Conference and then as a Young Scholar at the Southeastern Association of Law Schools’ Annual Conference. Professor Aleong would like to thank Professor Joel A. Mintz, Professor Michael Flynn and Professor Kathy Cerminara, her colleagues at NSU, for their review and discussion of this article and to thank her SEALS mentor, Professor Steven Ellman, New York Law School, for his guidance as well. Finally, Prof. Aleong would like to thank students Michael Pascucci and Laura Cancilla for their efforts as her research assistants.

2 U.S. FOOD & DRUG ADMIN., COMBATING COUNTERFEIT DRUGS: A REPORT OF THE FOOD AND DRUG ADMINISTRATION (2004), available at http://www.fda.gov/oc/initiatives/counterfeit/report02_04.pdf [hereinafter FDA REPORT 2004]. In some countries, the FDA even noted that the problem was so overwhelming that many patients had a better chance of getting fake medicine than a chance of getting authentic drugs. Id.

3 These fake “medicines” make up thirty percent of the market in some poorer countries. MSNBC, WHO to Crack Down on Fake Drugs, http://www.msnbc.msn.com/id/15730101/ (last visited June 15, 2007). In late 2006, the WHO created a taskforce entitled “IMPACT” (International Medical Products Anti-Counterfeiting Taskforce) to stop the deadly trade in fake drugs which studies suggest “kill thousands of people every year.” World Health Organization, WHO Launches Taskforce to Fight Counterfeit Drugs, http://www.who.int/bulletin/volumes/84/9/06-010906/en/ (last visited June 15, 2007). In 2003, the WHO had conducted a study to determine the global sale of counterfeit drugs and estimated I to be $32 billion, constituting 10% of all medicines sold worldwide. Ronald W. Buzzeo, Counterfeit Pharmaceuticals and the Public Health, WALL ST. J., Oct. 4, 2005, at A20.

4 Id. The FDA claims that a “relatively comprehensive system of laws, regulations, and enforcement by Federal and state authorities has kept drug counterfeiting rare in the US,” but did acknowledge that the
reaching consumers from the shelves of large, retail pharmacy chains have been well-documented. As a result the FDA has lifted the stay on a nearly fifteen-year-old regulation which requires distributors of prescription drugs to document the source of the drugs they peddle. In fact, the high risk of receiving fake or diverted drugs in the United States has been referred to as “pharmaceutical roulette” for millions of American patients.

Moreover, the incidence of counterfeit drugs is a growing problem in the United States. The Pharmaceutical Security Institute reported that the value of seized, counterfeit and diverted drugs in this country alone was almost $200 million in 2003, a sevenfold increase from 2002. Further, the U.S. Drug Enforcement Administration (DEA) reports

\[ \text{problem of counterfeit drug has been increasing. Id. Further, the FDA did state that the “exact prevalence rates [of counterfeit drugs] in the U.S. are not known.” Id.} \]

\[5\] See, e.g., KATHERINE EBAN, DANGEROUS DOSES: HOW COUNTERFEITERS ARE CONTAMINATING AMERICA’S DRUG SUPPLY (2005). Eban details how counterfeit drugs emanating from hot trailers, car trunks, a Miami strip club and other questionable sources arrived on the shelves of drugstores like CVS. Id. at __. In the interest of full disclosure, I was one of the prosecutors described in Ms. Eban’s book as I worked on counterfeit drug prosecutions in my capacity as Florida’s Health Care Fraud Priority leader. Id. at __. Also, Dateline NBC has done investigative reporting on the prevalence of counterfeit drugs in the United States’ legitimate marketplace. MSNBC, Inside the World of Counterfeit Drugs, http://www.msnbc.msn.com/id/13137839/page/6/ (last visited June 15, 2007).

\[6\] Anna Wilde Mathews & Heather Won Tesoriero, FDA to Order Tracking of Medicines, WALL ST. J., June 9, 2006, at A2. The FDA lifted the stay on the “pedigree” requirement provided in title 21 of the Code of Federal Regulations section 203.50, which requires unauthorized distributors of pharmaceuticals to provide a document detailing the distribution history of a pharmaceutical. 21 C.F.R. § 203.50 (2006).

\[7\] Middlemen have culled expensive and popular drugs from the legitimate market and diverted into a shadow market, where criminals have introduced counterfeit medication and then moved the drugs back into the mainstream distribution network. Gilbert M. Gaul & Mary Pat Flaherty, U.S. PRESCRIPTION DRUG SYSTEM UNDER ATTACK, WASH. POST, Oct. 19, 2003, at A15.

\[8\] The term diverted indicates drugs which have strayed out of the original distribution channel for which they were originally intended. Diverted drugs include drugs that were originally purchased by a government program such as Medicare, Medicaid or the Veterans’ Administration and then resold into the legitimate market. U.S. FOOD & DRUG ADMIN., FDA’S COUNTERFEIT TASK FORCE INTERIM REPORT (2003), available at http://www.fda.gov/oc/initiatives/counterfeit/report/interim_report.html [FDA INTERIM REPORT 2003] (last visited at June 16, 2007).

\[9\] Buzzeo, supra note 3.
that in 2006, 78.8% of state and local law enforcement agencies reported either high or moderate availability of diverted pharmaceuticals in their areas.10

The drug distribution system in the United States is porous and vulnerable. Drugs are usually not sold directly from a manufacturer to a dispensing pharmacy.11 Drugs weave their way through a complicated distribution chain that includes large and small distributors, authorized and non-authorized distributors, and even criminal hands often, before reaching dispensing pharmacies who might in turn sell unused product back into the distribution chain.12

This article will consider the following: (1) how prescription drugs are distributed in the United States; (2) whether the law currently contains adequate safeguards to protect the integrity of the drug supply from counterfeiters; (3) that courts could hold manufacturers and authorized distributors vicariously liable for the injury caused to patients by counterfeit drugs when those entities do not take special precautions to protect the drug supply as they bear a nondelegable duty of safe distribution; and (4) alternatively, whether Congress should go beyond existing tort principles by imposing strict liability on manufacturers and distributors of pharmaceutical drugs when counterfeit drugs injure patients, similar to the strict liability for hazardous waste imposed by

11 The “gold standard” for safe distribution had been when manufacturers sold directly to the three largest distributors in the country, who in turn sold directly to drug dispensing entities, thereby involving no other wholesalers in distribution. Gaul & Flaherty, supra note 7.
12 Regarding the seizure of more than 70,000 doses of counterfeit Viagra, Aaron Graham, who had been an investigator for both the government and for the pharmaceutical industry, commented to Dateline NBC, "You might think medicine goes straight from the factory to your pharmacy. But there’s actually a complex network of wholesalers who buy and sell surplus medicines. All it takes is some phony paperwork and some realistic packaging to let fake medicine slip into the system, and be shipped to local pharmacies nationwide. And criminals know it." Chris Hanson, MSNBC.com, Inside the World of Counterfeit Drugs, http://www.msnbc.msn.com/id/13137839/print/1/displaymode/1098/ (last visited June 16, 2007).
environmental laws such as the Resource Conservation and Recovery Act (RCRA)\textsuperscript{13} and the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA),\textsuperscript{14} since the occurrence of counterfeit rugs is both foreseeable\textsuperscript{15} and is the “social byproduct” of legitimate pharmaceutical manufacture and distribution.

**II. How Drugs Are Distributed in the United States**

Drugs in the United States generally do not travel straight from the line of production to the dispensing pharmacy. This serpentine maze provides a ripe environment for the infiltration of counterfeit, adulterated and diverted drugs.\textsuperscript{16}

The distribution system is primarily tiered among manufacturers, the “Big 3” distributors/drug wholesalers, secondary wholesalers\textsuperscript{17} and repackagers. The FDA has identified the three, most-common routes for drug sales in the United States, identifying the vulnerability of the distribution system to counterfeit, adulterated and diverted product

\textsuperscript{14} Id. §§ 9601-75 (2000).
\textsuperscript{15} On May 6, 2005, Cardinal Health promised to discontinue its pharmaceutical arbitrage desk which bought and sold drugs among secondary wholesalers because of the high incidence of counterfeit drugs in the distribution network in the United States. Heather Won Tesoriero, *Cardinal Health Ends Drug Trading*, WALL ST. J., May 6, 2005, at B2. Additionally, in its own Securities and Exchange Commission 8-K filing on September 22, 2005, AmerisourceBergen Corporation promised that effective October 1, 2005, it would purchase all of its branded and generic pharmaceuticals for distribution in the U.S. only from manufacturers. In the rare instances in which a manufacturer requires the Company to purchase products from an exclusive distributor, AmerisourceBergen would follow the manufacturer's requirements. This change was not expected to have a material impact on the Company's fiscal year 2006 earnings. AmerisourceBergen, Current Report (Form 8-K) (Sept. 23, 2005), available at http://www.amerisourcebergen.com/investor/phoenix.zhtml?c=61181&p=irol-SECText&TEXT=aHR0cDovL2NjYm4uMTBrd2l6YXJkLmNvbS94bWwwZmlsaW5nLmhbD9yZXVcRbmsmaXBhZ2U9MzY5ODI1NyZhDRhY2g9T04= (last visited June 17, 2007).
\textsuperscript{16} Corrupt wholesalers often solicit members of the distribution chain to resell discounted drugs to them for re-introduction into the nation’s drug supply and often buy drugs from criminal enterprises. *EBAN*, supra note 5, at 21–92.
\textsuperscript{17} Secondary” wholesalers buy selected drug products from wholesalers, and they resell to other wholesalers, including large wholesalers, and pharmacies. *FDA INTERIM REPORT 2003*, supra note 8. However, some fifteen regional distributors, which represent billions of dollars in drug sales do exist in addition to the “Big 3” distributors. *EBAN*, supra note 5, at 90.
as drugs pass through multiple hands before reaching patients. The “Big 3” wholesalers, Cardinal Health\textsuperscript{19}, McKesson Corp.\textsuperscript{20} and AmeriSource Bergen,\textsuperscript{21} which collectively account for nearly 90% of the primary wholesale market,\textsuperscript{22} sell drugs into a distribution web containing large governmental agencies, secondary wholesalers and

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{drug_distribution_models.png}
\caption{Drug Distribution Models}
\end{figure}

\ldots three models showing the movement of drugs through the U.S. drug distribution system. (The dotted lines indicate potential illegal sales.) In the simplest situation, the manufacturer sells directly to a retailer. However, in many instances, there can be one or more wholesalers, or even a repackager, who handles the drug before it reaches the retailer. It is in these intermediate steps, particularly when the wholesaler(s) and/or repackager(s) obtain products from sources other than the original manufacturer, that the greatest opportunities for compromising the security of the U.S. distribution system exist.]


\textsuperscript{22} FDA INTERIM REPORT 2003, supra note 8.
criminal actors. 23 “Repackagers” of drugs further obscure the origin of any particular drug when they break wholesale drugs in bulk containers into smaller units for sale to pharmacies or re-aggregate smaller units purchased as overstock from pharmacies into larger bundles for resale to wholesalers. 24 As a result of the multiple distributors and the repackaging, the true origin of drugs in this net remains obscure. 25

Although the government and wholesalers have maintained that legitimate reasons exist for so many entities to be involved in the distribution of drugs, 26 federal legislative history identifies the cycling of drugs, from one entity to another before drugs reach dispensing pharmacies, as the driving factor which fuels diversion of drugs. 27 The high cost of drugs, “virtually anonymous distribution channels,” 28 and high consumer demand compound the desire of counterfeiters to flood the marketplace with tainted drugs. In fact, the riches from such an illegal enterprise are great. 29 One FDA official even opined that

23 Id.
24 Id.
25 Even the New York State Attorney General to become concerned with the integrity and source of drugs that circulate in this web: 25 his concern was triggered after a Long Island, New York, teenager and liver transplant recipient received adulterated medication from a local CVS retailer that had traveled through a Miami strip club, a trailer, a laundry room and then ten other facilities before reaching the shelves at CVS. EBAN, Chart following Epilogue, supra note 5, at 358–59. Shortly after his mother injected him with the adulterated Epogen, Timothy Fagan, the teenage liver transplant recipient, convulsed at home and suffered radiating pain throughout his body. Timothy continued having these reactions after each injection until a staff person at CVS warned Tim’s mother that several vials of counterfeit Epogen bearing the same lot number as the Fagan’s drug had been found. Id. at 122–24.
26 The FDA stated that legitimate price differentials available because of temporary overstocks of drugs and quick turnaround for the temporary needs of pharmacies were among some reasons to include multiple wholesaling entities in the distribution chain. Id. The lobbyist organization for wholesale distributors, HDMA, maintains that wholesale distributors play a critical role in making sure that patients do not suffer from shortfalls of medication, although they admit that the wholesalers have no responsibility for ensuring that sufficient quantities of drugs are manufactured initially. HDMA, Product Availability/Drug Shortage, http://www.healthcaredistribution.org/issues_in_dist/product.asp.
28 Buzzeo, supra note 3.
29 Id.
“some of the experts are telling us it’s more lucrative to sell a counterfeit drug than it is [to sell] a narcotic such as heroin.”

This complex maze of distribution allows tainted medicine to penetrate the legitimate marketplace at multiple points in the process. In all too familiar patterns, criminals sell counterfeit, diverted and adulterated drugs to small, unscrupulous wholesalers who in turn introduce the drugs into the distribution network. As the FDA itself has recognized, criminals can now introduce counterfeit drugs at any point in the distribution process. Even a single counterfeiter can contaminated a nation’s drug supply at multiple levels of distribution.

Some may argue that the complicated system of distribution is “no one’s fault.” Nonetheless, manufacturers and the major drug wholesalers are responsible for the establishment of the overly complex and unnecessarily obtuse web. The activities that

---

30 Id.
31 FDA INTERIM REPORT 2003, supra note 8.
32 In fact, a high-level Vice-President at Cardinal Health, one of the three largest drug wholesalers in the United States, conspired with a drug counterfeiter and allowed thousands of doses of counterfeit plasma medicine into the back door of Cardinal Health, which was then distributed throughout the country. United States v. Spence, Carlow, No. 3:06-00047 (M.D. Tenn. 2006). Neil Spence, Vice President of Cardinal’s Plasma Division, was buying, on behalf of Cardinal Health, fragile plasma medicine from Michael Carlowe who trafficked in counterfeit and diverted medicine. Id. Another of America’s largest distributors, AmeriSource Bergen was the subject of an FDA and FBI investigation into its illegal diversion of drugs into the secondary market to boost profits. Heather Won Tesoriero & Gary Fields, FBI, FDA Investigate Big Drug Wholesaler, WALL ST. J., Sept. 19, 2003, at B1. That same drug counterfeiter, Michael Carlowe, was indicted not only in Tennessee regarding his transactions with Cardinal but also sentenced in Missouri for dealing in $42 million of diverted Lipitor. The Department of Justice announced that the district court in the Western District of Missouri had imposed a five-year sentence on Michael Carlow for his involvement in the multi-million dollar counterfeit Lipitor scheme in Case No. 4:05-cr-00315-ODS. Bradley J. Scholzman, U.S. Department of Justice, News Release: Florida Business Owner Pleads Guilty to $42 Million Lipitor Conspiracy, Nov. 3, 2006, available at http://www.usdoj.gov/usaow/mow/news2006/carlow.ple.htm (last visited June 16, 2007). Carlow was also indicted in Florida for repackaging millions of dollars of adulterated drugs in the laundry room of his home. State v. Carlow, No. SC02-2645 ( Fla. 2003) (indictment filed July of 2003) (alleging Racketeering, Conspiracy to Commit Racketeering, Organized Scheme to Defraud, Fraud and numerous other offenses all relating to his trade in counterfeit, diverted and adulterated drugs).
occur in this web are not “beyond the control” of manufacturers. Very clearly, manufacturers have voluntarily chosen not to engage in the business of distributing drugs to dispensing pharmacies. Further, they have chosen the group of distributors to whom they sell. In addition, all three major wholesalers decide for themselves from who they buy and to whom they sell drugs. Until recently, those largest wholesalers maintained pharmaceutical arbitrage divisions which scavenged the marketplace, buying from nearly all comers, drugs at the lowest expense possible. Clearly, the largest stakeholders in the pharmaceutical industry determine how medicine is distributed.

III. The Law Currently Does Not Contain Adequate Safeguards to Protect the Integrity of the Drug Supply from Counterfeiters.


In 1987, the federal government specifically enacted the Prescription Drug Marketing Act (PDMA) to curb diversion of prescription drugs which endangers public health.

---


34 EBAN, *supra* note 5, at 90. Manufacturers and large pharmacy retailers profit greatly from this web of a distribution system which “allows them to centralize their selling and purchasing and save billions in distribution costs.” Id.

35 Id. at n.22 (detailing when AmeriSource Bergen and Cardinal Health merely promised to discontinue the practice of buying drugs from the secondary market). In fact, when Cardinal Health announced it would stop purchasing products from this questionable source in May 2005, Cardinal acknowledged the risks posed by the source: Ridding itself of a profitable but problematic business Interest, Cardinal Health will shut down its Cardinal Health Pharmaceutical Trading operation, which buys and sells discounted and overstocked pharmaceuticals in the secondary distribution market. The move—announced in a letter to employees and suppliers May 6—follows recent legal action from New York State Attorney General Elliot Spitzer, who last month subpoenaed Cardinal and its two largest whole competitors as part of a high-profile investigation of drug sourcing, counterfeiting and the pharmaceutical supply chain. DeKiefer, *supra* note 41, at n.24 (citing James Frederick, *Cardinal Latest Wholesaler to Curb Secondary Dealing*, 27 DRUG STORE NEWS 8, 8 (2005), available at 2005 WLNR 8725663). McKesson has made no such pledge to discontinue purchasing drugs from the “grey market.” See McKesson Corporate, www.mckesson.com (last visited June 16, 2007).

The PDMA sought to end the recycling of drugs through the complex distribution system. In the text of the public law itself, Congress lamented that the American public could not trust the integrity of the drugs marketed in the United States. Although it created no new effective provisions itself, the Act amended numerous provisions of the Federal Food Drug and Cosmetics Act (FDCA). The PDMA sought to curtail numerous ills that Congress felt were contributing to the proliferation of tainted drugs in the United States drug supply which included: (1) the existence of the wholesale diversion market; (2) the resale in large volume of wholesale-priced drugs by entities other than the manufacturer or initial purchaser; and the illegal sale of adulterated drugs which began as physicians’ samples.

---

37 See S. REP. No. 100-303, 100th Cong., 2d Sess., 102 Stat. 95 (1988). “The purpose of the legislation is to curb operation of the diversion market for prescription drugs that operates outside of normal channels of distribution and makes it difficult to protect American consumers from mislabeled, subpotent, adulterated, expired, or counterfeit pharmaceuticals.” Id.

38 EBAN, supra note 5, at 107.

39 In Law 100-293 Section 2 Congress found that:

1. American consumers cannot purchase prescription drugs with the certainty that the products are safe and effective;
2. The integrity of the distribution system for prescription drugs is insufficient to prevent the introduction and eventual retail sale of substandard, ineffective, or even counterfeit drugs;
3. The existence and operation of a wholesale submarket, commonly known as the “diversion market”, prevents effective control over or even routine knowledge of the true sources of prescription drugs in a significant number of cases.


40 U.S.C.A. Popular Name Table for Acts of Congress.


43 The bulk resale of below wholesale priced prescription drugs by health care entities, for ultimate sale at retail, helps fuel the diversion market and is an unfair form of competition to wholesalers and retailers that must pay otherwise prevailing market prices.” Id. § 2(7).

44 “The existing system of providing drug samples to physicians through manufacturer's representatives has been abused for decades and has resulted in the sale to consumers of misbranded, expired, and adulterated pharmaceuticals.” Id. § 2(6).
Among its amendments to the FDCA, the PDMA required that drug wholesalers who were not “authorized distributors of record”\(^\text{45}\) to submit a statement identifying each sale of a drug in its lifetime before reaching a dispenser or being returned to a distributor.\(^\text{46}\) This identifying statement is commonly referred to as a “pedigree.”\(^\text{47}\) Pedigrees provide a transparent history of the source of a drug along with leads to investigators who want to trace the source of bad drugs.\(^\text{48}\) The pedigree requirement was Congress’ attempt to “restore accountability to the wholesale sector of the pharmaceutical market . . . .”\(^\text{49}\)

Regrettably, the imagined accountability in the drug supply chain promised by the PDMA was short-lived. Even in his signing statement, then President Ronald Reagan foreshowed a sluggish FDA effort to implement such accountability.\(^\text{50}\) Predictably, in response to cries from the drug industry that forcing them to provide histories of the drugs they sell would cripple the industry out of existence by both wholesalers\(^\text{51}\) and

\(^{45}\) *Id.* § 6(e)(1). The problematic elasticity of the definition of who is an authorized distributor is discussed below. See infra p. 11-12.

\(^{46}\) *Id.*


\(^{48}\) See WORKSHOP, *supra* note 55, at 19–20. The author notes that even dog breeders and car dealers must provide pedigrees of their wares. *Id.*


\(^{50}\) In his signing statement, the President said:

> Finally, although the lack of traceability of drug products in the diversion market is a valid concern that I share, the magnitude of the public health problem created by diverted drugs is still not clear. I am therefore also concerned by the provisions of the bill requiring use of substantial amounts of scarce Federal public health resources to police these practices.

*President’s Statement on Signing the Prescription Drug Marketing Act of 1987, 24 WEEKLY COMP. PRES. DOC. 519 (Apr. 25, 1988).*

\(^{51}\) In a Senate hearing before the passage of the PDMA, a representative of one of the wholesalers’ lobbies likened having to source medicine to being required to source real estate, a process which would make the cost of drugs dramatically higher and be operationally impossible for secondary wholesalers. *Prescription Drug Marketing Act of 1987: Hearing on H.R. Rep. 100-76 Before the H. Comm.’s Subcomm. on Oversight and Investigations*, 100th Cong. 1st Sess. 48–49 (1987) (statement of Ronald J. Streck, Vice President, National Wholesale Druggists Association).
even a manufacturer, the FDA reduced the requirement of a pedigree to a mere guidance opinion, in effect staying the implementation of pedigrees. Through a prolonged ten-year rulemaking process and the following decade, the FDA administratively negated the full pedigree requirement five times over nearly twenty years. On June 9, 2006 the FDA announced it was lifting the stay implementation of pedigrees, effective December 6, 2006. Even though numerous documented cases of

---

52 The manufacturer Smith Kline & French protested the pedigree requirement in an October 3, 1988, letter to the FDA. EBAN, supra note 5, at 385, 163 n._.
53 Pedigree requirements were explicitly defined by regulation by the FDA in 21 Code of Federal Regulations Sections 203.1 through 203.60. 21 C.F.R. §§ 203.1–.60 (2006).
54 On August 1, 1988 the FDA issued a guidance letter setting forth the agency’s preliminary views regarding the industry’s responsibilities under the PDMA. The letter stated to be an “authorized distributor” the type of ongoing relationship that needed to exist was only a “continuing business relationship in which I is intended that the wholesale distributor engage in wholesale distribution of a manufacturer’s prescription drug product or products. Letter from Daniel L. Michaels & Thomas S. Bozzo, Directors, FDA Office of Compliance, to Regulated Industry and Other Interested Persons (Aug. 1, 1988) (on file with author), available at http://www.fda.gov/oc/pdma/report2001/attachment-e.pdf. By stating that drug wholesalers only had to comply with existing recordkeeping practices of the industry, the FDA stayed the enforcement of a pedigree requirement, which wholesalers had never made an industry practice: The new law's requirements for State licensing of wholesale drug distributors and the attendant requirements for minimum standards for recordkeeping, storage, and handling of prescription drugs pose potential economic implications for wholesale drug distributors. Although the statute itself does not specify these minimum standards, Congress clearly intended that these standards match currently recommended practices within the wholesale drug sector. The recommendation by the House of Representatives’ Committee on Energy and Commerce for FDA to consider the Guidelines for the Inspection of Wholesales issued by the NABP provided explicit guidance on the specifications for these standards. FDA sought to conform the proposed minimum standards with the NABP guidelines and NWDA’s-related proposed uniform standards by limiting modifications to conformance with current language and to clarifications required for consistency with existing drug regulations. Thus, the proposed minimum standards are intended to mirror recommended practices already existing among drug wholesalers. The agency is not aware of the degree to which drug wholesalers comply with the various existing guidelines, but the agency believes that these represent the norm of current practices and procedures among drug wholesalers.

55 EBAN, supra note 5, at 386, 165 n._. The FDA finally promulgated a final rule regarding implementation of the pedigree in 1994, which required non-authorized distributors to include the name of each business who sold the drug starting with the manufacturer. 21 C.F.R. § 203.50.
56 In its press release, the FDA stated that in an effort to protect the public from counterfeit drugs, “... the FDA will fully implement regulations related to the Prescription Drug Marketing Act of 1987, which requires drug distributors to provide documentation of the chain of custody of drug products—the so-called “pedigree”—throughout the distribution system. Dep’t of Health & Human Servs., U.S. Food & Drug Admin., FDA Announces New Measures to Protect Americans from Counterfeit Drugs, FDA News, June 9, 2006, at P06-78, available at http://www.fda.gov/bbs/topics/NEWS/2006/NEW01386.html [hereinafter FDA News].
counterfeit drugs had come to light, the agency claimed it was lifting the stay because of the availability of technology to help distributors comply with pedigree requirements and that small wholesalers were no longer voicing complaints about compliance with the pedigree regulation.  

Sadly, a fully-implemented, federal pedigree requirement is still not a reality. In *RxUSA Wholesale, Inc. v. Department of HHS*, secondary wholesalers, who would not qualify as “authorized distributors” under the PDMA, alleged that the PDMA itself and/or FDA regulation 203.50 implementing the pedigree requirement were/was an unconstitutional violation of Equal Protection and Due Process under the 14th Amendment. Claiming a violation of Equal Protection, the wholesalers argued that the pedigree regulation constituted disparate treatment in as much as it arbitrarily and capriciously required non-authorized distributors to trace products back to the manufacturer, even though authorized distributors did not have to do so, thus preventing non-authorized distributors from conducting business. In addition, the wholesalers argued that FDA regulation 203.50 interpreting the PDMA violated the Due Process Clause requiring only non-authorized distributors to source a drug to the manufacturer they contended had no rational relation to any legitimate state interest and that it was an

---

58 The FDA claimed it had not received much complaint from small wholesalers about the impact of requiring pedigrees, and finally recognized it could no longer justify delaying the requirement. FDA NEWS, supra note 65, at n.64.
60 Id. at 16.
61 To source means to identify the sales history of a drug.
erroneous interpretation of the PDMA, which requires that wholesale customers be informed of “all prior sales of the product.”

On November 30, 2006, seven days before the long-anticipated effective date of a federal pedigree requirement, a district court for the Eastern District of New York issued a preliminary injunction staying the implementation of the federal pedigree requirement. The court disregarded the Government’s anemic laches claim that it would suffer prejudice if the Court delayed the implementation of the pedigree rule on the basis that the FDA itself had delayed the rule’s implementation for so long already. Regrettably, no other federal legislation currently requires pedigrees in the distribution chain. The need for a fully-implemented PDMA is apparent.

If federal pedigrees become mandatory, the definition of who qualifies as an exempt “authorized distributor” under the PDMA is too broad to provide real protection to consumers. Under the PDMA, an “authorized distributor” is exempt from having to produce any pedigree when transacting pharmaceuticals. In 1999, the FDA

---

62 Because the FDA had maintained the “status quo” for nearly twenty years of not requiring non-authorized distributors to produce pedigrees sourcing a drug back to the manufacturer pursuant to the 1999, to now require wholesalers to do that would be erroneous. Id.

63 The Court reasoned that the preliminary injunction as merely a “temporary reprieve of the Rule taking effect.” RxUSA Wholesale, Inc., 467 F. Supp. 2d at 307.

64 Id.


66 The known threat of counterfeit drugs which spawned only a handful of investigations in the 1990s now has jumped nearly ten-fold. Afia K. Asamoa, Not as Easy As It May Appear, 61 FOOD & DRUG L. J. 385 (2006) (citing FDA REPORT 2004, supra note 2).

67 21 Code of Federal Regulations Section 203.50 provides in section (a) the following: Identifying statement for sales by unauthorized distributors. Before the completion of any wholesale distribution by a wholesale distributor of a prescription drug for which he seller is not an authorized distributor of record to another wholesale distributor or retail pharmacy, the seller shall provide to the purchaser a statement identifying each prior sale, purchase or trade of such drug. 21 C.F.R. 203.50(a) (2006). The regulation goes on to specify what information shall be contained in that identifying statement. See id.
promulgated its final rule and deemed that, without receiving any further governmental scrutiny, an “authorized distributor” is anyone with an “ongoing relationship” with a manufacturer. Thus, no governmental entity exercises oversight in certifying which entities are “safe enough” to be trusted without a traceable history of distribution. Even when the FDA issued guidance documents for the drug industry regarding compliance with the PDMA in 2006, the nonbinding recommendations provided no additional procedures to clearly identify who is an authorized distributor of record. Ironically, even the Healthcare Distribution Management Association (HDMA), the lobbyist organization for wholesale distributors noted that the definition of an authorized distributor under the PDMA should be enhanced to make any current pedigree requirements meaningful.

68 The PDMA defines as “authorized distributor” as a “distributor with whom a manufacturer has established an ongoing relationship to distribute such manufacturer’s products.” Id. § 203.1(b). An “ongoing relationship” is further defined in subsection (u) as the following: American consumers

(u) Ongoing relationship means an association that exists when a manufacturer and a distributor enter into a written agreement under which the distributor is authorized to distribute the manufacturer’s products or a period of time or for a number of shipments. If the distributor is not authorized to distribute a manufacturer’s entire product line, the agreement must identify the specific drug products that the distributor is authorized to distribute. Id. § 203.1(u).


70 In a press release posted on its website on June 9, 2006, following the FDA lifting the stay on the federal pedigree requirement, the HDMA suggested changing the definition of “authorized distributor” and “distributor” in general to the following:

“Authorized Distributor of Record” means a drug distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer’s product. An ongoing relationship is deemed to exist when a drug distributor, including any affiliated group, as defined in Section 1504 of the Internal Revenue Code, of which the distributor is a member: a) Is listed on the manufacturer’s list and the list is updated monthly, or b) Has a written agreement currently in effect with the manufacturer, or c) Has a verifiable account with the manufacturer and minimal transaction or volume requirement thresholds as follows: 5,000 sales units per company within twelve (12) months or twelve (12) purchases (invoices) from the manufacturer within twelve (12) months.
B. State Law Attempts to Source the Drug Distribution Chain

Faced with the federal pedigree requirement effectively stuck in purgatory, some states did undertake the burden of attempting to craft for consumers meaningful protection for consumers against counterfeit, adulterated and fake medicines. Florida, Nevada, California and New York led the nation in attempting to pass laws and

“Distribution or wholesale distribution” means the distribution of prescription drugs to persons other than a consumer or patient, but does not include:

a) Intracompany sales;

b) The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;

c) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

d) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control;

e) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons;

f) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug under a prescription executed in accordance with section ___ of this chapter;

g) The distribution of drug samples by manufacturers’ and authorized distributors’ representatives;

h) The sale, purchase, or trade of blood or blood components intended for transfusion;

i) Drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with section ______ of this chapter or the Board’s/Departments’ regulations; or

j) The sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use.

“Distributor or wholesale distributor” means any person engaged in the distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers’ and distributors’ warehouses, chain drug warehouses, and drug warehouses; and retail pharmacies that conduct drug distributions as defined in this section.


71 Nevada enacted the toughest controls in the country who can qualify as a wholesaler in the state, thereby attempting to squeeze out the criminal element in the whole shadow market. Gilbert M. Gaul & Mary Pat Flaherty, Nevada Gets Tough, With Mixed Results, WASH. POST, Oct. 22, 2003, at A16. An owner of a wholesaler must employ an authorized representative with 6,000 of experience, Id., must submit fingerprints of the owner with a complete list of employees/agents; only if a corporation is publicly traded is the owner exempt from the fingerprinting and employee list requirements. NEV. ADMIN. CODE § 639.593 (2005). However, although the regulation shoved may wholesalers out of the state, the Nevada model cannot clean up the nation’s supply as wholesalers merely moved across state lines and continued to distribute bad medicine into the porous national drug supply. Gilbert M. Gaul & Mary Pat Flaherty,
administration regulations cracking down on the secondary wholesale market. Among all those states, Florida appeared to be a shining example of regulation.

Florida’s legislative experience, however, proved disappointing and ineffective. In 2003, the 17th Statewide Grand Jury in Florida issued a scathing report summarizing the great danger posed when counterfeiters and diverters infiltrate the legitimate distribution stream of prescription drugs. The Florida legislature embraced the Grand Jury’s recommendation for a strong state pedigree law. It passed the Prescription Drug Protection Act of 2003, which amended many provisions of Florida’s Food Drug and

---

Nevada Gets Tough, With Mixed Results, WASH. POST, Oct. 22, 2003, at A16. However, Nevada did enact a stringent pedigree requirement; Nevada Administrative Code section 639.603 requires wholesalers to pass pedigrees when the wholesaler is either (1) not an authorized distributor of a medicine or (2) when a wholesaler bought a drug from a source other than the manufacturer. NEV. ADMIN. CODE § 639.603.


The Grand Jury noted that tainted drugs move easily through the national drug distribution chain because of the failure of state and federal agencies to enforce the law and because of the “complicity of the wholesalers who turn a blind eye to the corrupt practices of other wholesalers that supply them with some of their pharmaceuticals.” SEVENTEENTH STATEWIDE GRAND JURY, FIRST INTERIM REPORT, No. SC02-2645 (Fla. 2003), available at http://myfloridalegal.com/grandjury17.pdf [hereinafter FIRST INTERIM REPORT OF GRAND JURY]. The Grand Jury also noted that the 422 wholesale distributors of drugs in Florida, who bought and sold drugs amongst themselves before passing them on to dispensing entities, permitted an “alarming percentage” of illegally purchased drugs from the black market; the Grand Jury further noted that many of the wholesalers in Florida were “unqualified, inexperienced, irresponsible and incompetent.” Id.; see also SEVENTEENTH STATEWIDE GRAND JURY, SECOND INTERIM REPORT, No. SC02-2645 (Fla. 2003), available at http://myfloridalegal.com/interimjury17.pdf. (The Grand Jury went on to illustrate the millions of dollars the Medicaid program was losing as Medicaid recipients and corrupt infusion clinics resold to the black market medication paid for the Medicaid program, all medication which criminals reintroduced into the wholesale distribution system).

FIRST INTERIM REPORT OF GRAND JURY, supra note 83.


16
Cosmetic Act. In addition to strengthening licensing requirements for wholesalers\textsuperscript{77} and increasing felony penalties for counterfeiters/diverters\textsuperscript{78} and non-compliant wholesalers,\textsuperscript{79} the state extended its administrative rule requiring pedigree papers to travel with the identified most “vulnerable drugs” in the state,\textsuperscript{80} and it required pedigree papers to accompany all drugs distributed in the state.\textsuperscript{81} What qualified as a

\textsuperscript{77}The legislative history of this section severely curtails who might qualify as a wholesaler in the state and reads in its preamble to the changes made by the 2003 Prescription Drug Protection Act:

\textit{Legislative findings and intent.}--Based on the report of the Seventeenth Statewide Grand Jury in its First Interim Report the Legislature finds that prescription drugs brought into the state by wholesalers are being relabeled and falsely represented as being of a higher dosage by other wholesalers in order to charge higher prices for those drugs and that counterfeit substances labeled as genuine pharmaceuticals are being distributed, thereby causing an extreme danger that persons eventually receiving the drugs by prescription are receiving ineffective drugs in nontherapeutic doses, or even receiving dangerous or unwholesome substances, with the result that the health and well-being of the public is at risk. The Statewide Grand Jury also found that the lack of an effective pedigree paper requirement has resulted in the inability of prescription drug users to have confidence in the purity and efficacy of the drugs they use. The Statewide Grand Jury further noted that present laws do not allow effective criminal prosecution of persons involved in such false representations. It is the intent of the Legislature that the statutory changes and recommendations outlined in the Statewide Grand Jury's report be implemented as provided by this act.

\textit{Id.}

\textsuperscript{78}The legislature elevated all criminal offenses relating to counterfeit and adulterated drugs to felonies of the second degree or higher. \textsc{Fla. Stat. Ann} § 499.0691 (West 2006).

\textsuperscript{79}\textit{See Id.} \textsc{§} 499.005

\textit{Laws 2003, c. 2003-155, § 4, inserted . . . (28), relating to failure to obtain a pass or pedigree paper; and added subsec. (29), relating to receipt of prescription drugs without pedigree papers. Subsec. (7) formerly read:}

\textit{“(7) The giving of a false guaranty or false undertaking with respect to a drug, device, or cosmetic, except by a person who relied on a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in this state from whom she or he received in good faith the drug, device, or cosmetic.”}

\textit{Id.}

\textsuperscript{80}The Florida Department of Health previously had the power to require wholesalers to provide complete pedigrees, including all prior sales and unique identifying lot numbers, that it placed a drug on a “specified list.” \textsc{Fla. Stat.} \textsc{§} 499.0121(6)(e) (2005). The Department could place a drug on the list of specified drugs if the department had seized or issued a stop sale notice on the drug because of the adulteration, counterfeiting or diversion of the prescription from any legal distributions channels or if the U.S. FDA or other government regulator responsible for the sale or distribution of prescription drugs in another state of such contamination of a drug in the legitimate marketplace, so long as the prescription drug satisfied one of the following criteria:

\begin{enumerate}
  \item [(I)] The prescription drug is included among the top 150 prescription drugs for which the state has incurred the highest amount of Medicaid claims in the most recently ended state fiscal year;
  \item [(II)] The prescription drug is available for normal prescription use in dosages or strengths that have a wholesale cost of $200 or more;
  \item [(III)] The prescription drug is used extensively for patients with human immune deficiency virus, acquired immune deficiency syndrome, cancer, or other serious, life-threatening conditions, where drug non-responsiveness would not be considered to be medically unusual;
  \item [(IV)] The prescription drug is an injectible drug;
\end{enumerate}
The term pedigree under Florida law was strictly defined as a document containing the lot number of the prescription drug and all sales information regarding it. The

(V) The prescription drug is subject to a special, limited distribution process and is not generally old to wholesale distributors by the manufacturer of the prescription drug;

(VI) The department has found not less than five instances where statements required pursuant to paragraph (d) for the prescription drug were not passed on other than because of unintentional oversight, or have been passed on by or to a wholesale distributor and such statements were fraudulent; or

(VII) A shipment of a prescription drug has been reported to a law enforcement agency as having been stolen or as missing.

§ 499.0121(6)(e)(3)(a)-(VII) (2005). The Department of Health, after consultation with the Drug Wholesaler Advisory Council, Id. §499.0121(6)(e)(3)b., would promulgate a rule placing drugs on the “specified drug” list. Id. The list of specified drugs appear in Florida’s Administrative Code. FLA. ADMIN. CODE ANN. r. 64F-12-001(2)(y)(2005). That list includes:

1. Bextra (valdecoxib);
2. Celebrex (celecoxib);
3. Combivir (lamivudine/zidovudine);
4. Crixivan (indinavir sulfate);
5. Diflucan (fluconazole);
6. Epivir (lamivudine);
7. Epogen (epoetin alfa);
8. Gamimune (globulin, immune);
9. Gammagard (globulin, immune);
10. Immune globulin;
11. Lamisil (terbinafine);
12. Lipitor (atorvastatin calcium); (fully effective 3/29/2004)
13. Lupron (leuprolide acetate);
14. Neupogen (filgrastim);
15. Nutropin AQ (somatropin, e-coli derived);
16. Pangobulin (globulin, immune);
17. Procrit (epoetin alfa);
18. Retrovir (zidovudine);
19. Risperdal (risperidone);
20. Rocephin (ceftriaxone sodium);
21. Serostim (somatropin, mannnalian derived);
22. Sustiva (efavirenz);
23. Trizivir (abacavir sulfate/lamivudine/zidovudine);
24. Venogobulin (globulin, immune);
25. Viagra (sildenafil citrate);
26. Videx (didanosine);
27. Viracept (nelfinavir mesylate);
28. Viramune (nevirapine);
29. Zerit (stavudine);
30. Ziagen (abacavir sulfate);
31. Zocor (simvastatin);
32. Zofran (ondansetron);
33. Zoladex (goserelin acetate); and
34. Zyprexa (olanzapine).

Id.

Contraband legend drug” means any adulterated drug, as defined in s.499.006, any counterfeit drug, as defined in this section, and also means any legend drug for which a pedigree paper does not exist, or for which the pedigree paper in existence has been forged, counterfeited, falsely created, or contains any altered, false, or misrepresented matter.

Id.
document was to begin with the sale form the manufacturer and to include all subsequent sales information until the drug was dispensed to a patient.82

Unfortunately, Florida’s stringent pedigree requirement never went into effect. The effective date of the newly defined pedigree was to be July 1, 2006,83 and the pharmaceutical manufacturers and distributors mounted an assault in Florida’s 2006 legislative session to make sure that requirement would not become effective.84 At their urging, the Florida legislature amended the definition on what qualified as a pedigree, tacking that alternate definition to a free cancer drug donation bill.85 The new provision alternatively defined a “pedigree” as merely a document which states the name and strength of a drug accompanied by a promise by the manufacturer that "[this wholesale distributor purchased the specific unit of the prescription drug directly from the manufacturer.”86 This change eliminates the ability of law enforcement officers,

82 “Pedigree paper” means:
(b) Effective July 1, 2006, a document in a form approved by the Department of Health and containing information that records each distribution of any given legend drug, from sale by a pharmaceutical manufacturer, through acquisition and sale by any wholesaler or repackager, until final sale to a pharmacy or other person administering or dispensing the drug. The information required to be included on a legend drug's pedigree paper must at least detail the amount of the legend drug, its dosage form and strength, its lot numbers, the name and address of each owner of the legend drug and his or her signature, its shipping information, including the name and address of each person certifying delivery or receipt of the legend drug, and a certification that the recipient has authenticated the pedigree papers. It must also include the name, address, telephone number and, if available, e-mail contact information of each wholesaler involved in the chain of the legend drug's custody. The department shall adopt rules and a form relating to the requirements of this paragraph no later than 90 days after the effective date of this act.

Id. § 31 (b).

83 Id.

84 When I spoke in front of the Florida Senate Judiciary Committee on April 25, 2006, I was the only person present who testified against changing the law while representatives from McKesson, Cardinal and AmeriSource Bergen sat with a bevy of lobbyists for other wholesalers and State Representative Homan to register the drug industry's objection to the pedigree requirement. Those drug industry representatives stayed in Tallahassee until the pedigree law was changed after 11 p.m. on the very last day of the 2006 legislative session. See supra note 91.

85 After HB 685 (regarding just pedigrees and drug distribution ), HB 1397 (regarding the distribution of prescription drugs by veterinarians ) and SB 926 (regarding just pedigrees and drug distribution of prescription drugs), the drug industry through House and Senate representatives tacked the change in the pedigree requirement on to a free drug donation program for cancer patients in HB 371 and SB 1310.

86 The alternate definition of “pedigree” reads:
customers and agencies to find with the unique lot number from the pedigree paper the source of counterfeit drugs.\textsuperscript{87}

One minute prior to midnight on the very last day of Florida’s 2006 legislative session. The American Cancer Society asked Florida Governor Jeb Bush to veto HB 371, which would create a free drug-donation program it had steadily supported during the legislative session, because “the risks to cancer patients through any weakening of the state’s tough prescription drug safety law appear to outweigh the benefits of a new program whose merits are not yet established.”\textsuperscript{88} Sadly, Governor Bush signed the bill into law in June of 2006.\textsuperscript{89}

\textsuperscript{2} A statement, under oath, in written or electronic form, confirming that a wholesale distributor purchases and receives the specific unit of the prescription drug directly from the manufacturer of the prescription drug and distributes the prescription drug directly, or through an intracompany transfer, to a chain pharmacy warehouse or a person authorized by law to purchase prescription drugs for the purpose of administering or dispensing the drug, as defined in s. 465.003. For purposes of this paragraph, the term “chain pharmacy warehouse” means a wholesale distributor permitted pursuant to s. 499.01 that maintains a physical location for prescription drugs that functions solely as a central warehouse to perform intracompany transfers of such drugs to a member of its affiliated group as described in s. 499.0121(6)(h).  

a. The information required to be included pursuant to this subparagraph must include:
\begin{itemize}
  \item[(I)] The following statement: “This wholesale distributor purchased the specific unit of the prescription drug directly from the manufacturer.”
  \item[(II)] The manufacturer’s national drug code identifier and the name and address of the wholesaler and the purchaser of the prescription drug.
  \item[(III)] The name of the prescription drug as it appears on the label.
  \item[(IV)] The quantity, dosage form, and strength of the prescription drug.
\end{itemize}

b. The wholesale distributor must also maintain and make available to the department, upon request, the point of origin of the prescription drugs, including intracompany transfers; the date of the shipment from the manufacturer to the wholesale distributor; the lot numbers of such drugs; and the invoice numbers from the manufacturer.

\textsuperscript{87} The requirement that a wholesaler maintain receipts of sale and present them if asked for them was meaningless as the entire state of Florida had so few drug inspectors. See \textit{FIRST INTERIM REPORT OF GRAND JURY}, supra note 83, at 2, 18. There exists in Florida approximately 422 licensed wholesalers in the prescription drug industry. In addition, there are approximately 977 wholesalers outside of the state of Florida that are licensed by the State to ship prescription drugs into Florida . . . .

\textsuperscript{88} In a letter dated May 17 2006, Michael Kasper, M.D., Chairman of the Board/President of the American Cancer Society wrote the following to Governor Bush:

The promise of a lesser financial burden to particularly needy cancer patients means little if the prescription drugs provided to them could put their lives in jeopardy. While the cancer drug donation program is a viable concept that could ease some financial worries for some cancer patients, it is not the best solution to help them cover the costs of essential medications. Unless the state’s prescription drug safety law remains strong and enforceable, the risks associated with weaker regulations cannot be ignored.

\textsuperscript{89}
As well-intentioned as they might be, individual state efforts alone will not secure the drug supply in the United States. Drugs pour seamlessly among billion-dollar wholesalers, smaller wholesalers and retailers throughout the United States. What drugs originate in one state easily reach all parts of the country. A patchwork of conflicting state regulations will indeed be cumbersome for industry without ever uniformly ensuring the safety of medicine. A uniform legal theory, as well as a codified federal, legal duty,

patients, the greater concern to our organization is overall patient safety. In other words, Governor, we feel that it is more important to save lives than to save money.

It truly disappoints us to be in a position to recommend that you veto a bill that includes a positive new tool in the fight against cancer, but we feel the greater good would be served by staying the course with the drug pedigree process in current statute.

Letter from Michael Kasper, M.D., Chiarman of the Board/President, American Cancer Society, to John Ellis Bush, Governor of Florida (May 17, 2006) (on file with the American Cancer Society)


The FDA stated the ability of bad drugs to reach all parts of the distribution system:

Investigations performed by Federal and State authorities have repeatedly shown the existence of illicit nationwide networks designed to capitalize on inadequate due diligence performed by members of the drug distribution system in order to introduce potentially unsafe diverted counterfeit drugs in the U.S. drug distribution system.

U.S. FOOD & DRUG ADMIN., FDA’S COUNTERFEIT TASK FORCE INTERIM REPORT (2003), available at http://www.fda.gov/oc/initiatives/counterfeit/report/interim_report.html [FDA INTERIM REPORT 2003] (last visited at June 16, 2007). While manufacturers themselves may sell only to a handful of large distributors, the distributors buy drugs from other sources such as each other and other small wholesalers. “[T]hese secondary market sale are the primary, if not the exclusive means by which [tainted] drugs enter the bloodstream of the unwary.” Donald DeKieffer, Trojan Drugs: Counterfeit ad Mislabeled Pharmaceuticals in the Legitimate Market, 32 AM. J.L. & MED. 325, 327 (2006). Counterfeiter Michael Carlowe, who lived in Florida and repackaged drugs in his laundry room, infected the drug supply in Missouri, Tennessee, and the drug supply of national wholesaler Cardinal Health at the very least. See supra, notes 37–40 and accompanying text.

It is the very gaps among conflicting state ad federal regulations and the complexity of the labyrinth of that patchy regulation which give rise to the opportunity to introduce tainted drugs in one area with laxer regulation that then flow undetected through all tributaries of the national distribution system. DeKieffer, supra, at330-31.
is necessary to hold all parts of the drug distribution system accountable for bad medicine it circulates which injure patients.

IV. The “Good Humor” of Prescription Drugs: the Non-Delegable Duty of Safe Distribution Which Manufacturers and All Distributors Should Bear

Generally, manufacturers and distributors who are part of a business enterprise may escape liability for the enterprise’s negligence by making use of independent contractors. However, even though not all independent contractors of a putative employer are agents of the employer, some courts have concluded that as a matter of public policy, all the employers in an enterprise should be responsible for the torts of independent contractors “who are carrying out the work of the enterprise.” A nondelegable duty may arise by statute, contract or common law. The court’s imposition of a nondelegable duty presupposes that, in certain circumstances, the

---

93 An employer who hires an independent contractor is not generally liable for the contractor’s negligence. RESTATEMENT (SECOND) OF TORTS § 409 (1965); see Pusey v. Bator, 762 N.E.2d 968, 972 (Ohio 2002) (“[A]n employer is generally not liable for the negligent acts of an independent contractor”); Sloan v. Atlantic Richfield Co., 552 P.2d 157 (Alaska 1976) (holding that no wrongful death recovery should be imposed in favor of an employee of an independent contractor against the possessor/owner of land upon a theory of vicarious liability); see also Van Arsdale v. Hollinger, 437 P.2d 508, 513 (Cal. 1968) (noting that the independent contractor general defense was “now primarily important as a preamble to the catalog of its exceptions”).


95 The California Supreme Court noted that it has every reason to believe that American courts would begin stripping away the principle of nonliability for contractees who employ independent contractors, thereby allocating the risk of the independent contractor’s negligence to the general entrepreneur. Van Arsdale, 437 P.2d at 512 (citation omitted).


97 Van Arsdale, 437 P.2d at 512 (citation omitted). In fact, Congress could codify a nondelegable duty of safe distribution for both manufacturers and all distributors adopting the same rationale articulated in this section to support a judicial finding of the existence of a nondelegable duty.
employer of the independent contractor is “in the best position to identify, minimize and administer the risks involved in the contractor’s activities.” 98

An employer of an independent contractor has a nondelegable duty to care for delegated work negligently performed by the contractor 99 when the business enterprise engaged in is either (1) inherently dangerous 100 /generally hazardous activity 101 or (2) poses a peculiar risk of substantial harm to the public in absent undertaking special precautions. 102 Although some courts have blurred the categories of nondelegable duties by defining an inherently dangerous/generally hazardous activity as an activity which poses a peculiar risk of substantial harm in the absence of special precautions, 103 sounder reasoning keeps the two categories distinct. 104 When an activity poses a great risk of harm to the public against which the public has little or no ability to protect themselves because of the specialized knowledge involved in an industry, that activity should not need to be “inherently dangerous” to trigger a nondelegable duty.

98 Wilson v. Good Humor Corp., 757 F.2d 1293, 1301 (D.C. Cir. 1985)
100 DOBBS, supra note 104, at § 337. “[I]nherently dangerous” has also been defined as “unusually hazardous.” Wilson, 757 F.2d at 1303.
101 Id. (holding that
102 The Restatement (Second) of Torts clarifies the concept of a nondelegable duty when enterprise activity poses the special risk of physical harm:

One who employer an independent contractor to do work which the employer should recognize as likely to create during its progress a peculiar risk of physical harm to others unless special precautions are taken, is subject to liability for physical harm caused to them by the failure of the contractor to exercise reasonable care to take such precautions, even though the employer has provided for such precautions in the contract or otherwise.

RESTATEMENT (SECOND) OF TORTS § 416 (1965)

103 “Work is inherently dangerous when it creates a peculiar risk of harm to others unless special precautions are taken.” Pusey v. Bator, 762 N.E.2d 968, 973 (Ohio 2002) (holding hiring armed guards to protect property was inherently dangerous activity as the employer could foresee that an armed confrontation might be required to do the job); Some courts have blurred the distinction blurred the distinction between work of a peculiar risk and inherently dangerous work when discussing the finding of a nondelegable duty. See e.g. Privette v. Superior Cty, 854 P.2d 721, 723 (Cal. 1993) (“Under the peculiar risk doctrine, a person who hires an independent contractor to perform work that is inherently dangerous can be held liable for tort damages when the contractor's negligent performance of the work causes injuries to others.”)
104 Wilson, 757 F.2d at 1303 (reasoning that cases should be read to suggest that two distinct types of independent contractor activity can bring an employer within the nondelegable duty exception to vicarious liability).
A business enterprise is inherently dangerous if danger exists in doing the activity, regardless of the method used and no matter how skillful the independent contractor may be at a given activity.\textsuperscript{105} Conversely, an activity is not inherently dangerous if proper precautions can minimize its risk of injury.\textsuperscript{106} Typically associated with strict liability, inherently dangerous work does not require negligence on the part of the independent contractor for the principal to be directly liable.\textsuperscript{107}

An activity represents a peculiar risk in situations when the activity will likely cause injury to others unless special precautions are taken.\textsuperscript{108} A peculiar risk includes a danger resulting directly from the work done and not from the collateral negligence of the contractor in the operative, easily controlled details of the work.\textsuperscript{109} However, no bright-line rule exists to define when an activity represents a peculiar risk.\textsuperscript{110} The peculiar risk must be foreseeable to the employer at the time of contracting,\textsuperscript{111} and the activity must

\begin{footnotesize}
\textsuperscript{105} See \textit{Restatement (Second) of Torts} § 427(b) (1965)

It is not, however, necessary to the employer’s liability that the work be of a kind which cannot be done without a risk of harm to others, or that it be of a kind which involves a high degree of risk of such harm, or that the risk be one of very serious harm, such as death or serious bodily injury. It is not necessary that the work call for any special skill or care in doing it. It is sufficient that work of any kind involves a risk, recognizable in advance, of physical harm to others which is inherent in the work itself.

\textit{Id.}

\textsuperscript{106} See \textit{id.} § 427.

\textsuperscript{107} Privette v. Superior Court of Santa Clara County, 854 P.2d 721, \textbf{723} (Cal. 1993).

\textsuperscript{108} Restatement (Second) of Torts provides that a “peculiar risk” arises when a risk is “peculiar to the work to be done and arises out of its character, or out of the place where it is to be done, against which a reasonable [person] would recognize the necessity of taking special precautions.” \textit{Restatement (Second) of Torts} § 413 cmt. b. (1965).

\textsuperscript{109} Routine, predictable dangers are not peculiar risks as employers can expect the contractor to follow recommended safety procedures to avoid the routine danger. In \textit{Sievers v. McClure}, the court refused to holding an employer liable for the death of a contractor’s employee by denying to label the danger of falling of a sloped roof during a roofing contract a “peculiar risk” because no reasonable mind could find that the risk of falling from a sloped roof was abnormal to a contract to install a roof. 746 P.2d 885, 888 (Alaska 1987).

\textsuperscript{110} Wilson v. Good Humor Corp., 757 F.2d 1293, 1304 (D.C. Cir. 1985); Red Roof Inns, Inc. v. Purvis, 691 N.E.2d 1341, 1344-46 (Ind. Ct. App. 1998) (analyzing the nature of the work and the conditions under which it was performed to determine whether the risk of a roofer falling off a roof is an ordinary or peculiar risk).

\textsuperscript{111} Eastern Airlines v. Joseph Guida & Sons Trucking Co., 675 F. Supp.1391, 1395-96 (E.D.N.Y. 1987) (holding that the job of driving through an airport at night in order to deliver top soil was not an inherently dangerous activity for a truck driver).
\end{footnotesize}
encompass a probability of harm to others, not just a possibility.112 The peculiar risk doctrine differs from the general concept of a nondelegable duty in that a peculiar risk does not require abnormally great risk and holds an employer vicariously liable for the negligence of a contractor.113

Because counterfeit medicine poses a peculiar risk of harm to patients, manufacturers of pharmaceuticals who sell to authorized distributors who buy and sell from other wholesalers bear a nondelegable duty of ensuring the safety and integrity of the medicines they peddle.114 Manufacturers and authorized distributors have contractual relationships with each other,115 and distributors buy and sell amongst themselves frequently.116 Both inter-relationships appear very similar to the long-term, independent-contractor relationship between Good Humor Corporation and the vendors who sold its ice cream.117 Just as the Wilson vendors performed the bulk of Good Humor’s business in the completely foreseeable setting of a curbside littered with the peculiar risk of children,118 drug distributors now perform the bulk of a drug manufacturers’ business in a market littered with counterfeit, adulterated and diverted drugs.

112 Pusey v. Bator, 762 N.E.2d 968, 973 (Ohio 2002). “The exception does not apply, however, where the employer would reasonably have only a general anticipation of the possibility that the contractor may be negligent in some way and thereby cause harm to a third party.” Id.
113 Privette v. Superior Court of Santa Clara County, 854 P.2d 721, 725 (footnote 2) (Cal. 1993).
114 Authorized distributors and secondary wholesalers who buy directly from a contaminated source would be negligent themselves and thus bear direct liability.
115 In order to be an “authorized distributor” under federal law, the distributor must have that contractual relationship with the manufacturer. Supra at 15 (footnote 69).
116 Supra at 6 (footnote 19).
117 Wilson, 757 F.2d at 1306; contra Riviera v. Flav-O-Rich, 876 F. Supp. 373 (D. P.R. 1995). In Riviera, the court held that under Puerto Rico law, an ice cream truck owner was not ice cream manufacturer's “independent contractor,” but was merely purchaser of its products, and thus, manufacturer was not liable for alleged negligence of truck owner's employee in connection with child's falling from truck; manufacturer had no control over manner, means, or results of owner's work, fact that owner received discount when he bought more than $2,500 of manufacturer's products in any month was not contract for owner to sell $2,500 worth of products per month, and owner could sell other manufacturers’ products. Riviera, 876 F. Supp. at 384.
118 Wilson, 757 F.2d at 1306.
Just as Good Humor chose not to inform its vendors or take precautions against the known and specific dangers to children who purchase ice cream from its vendors, drug manufacturers and large distributors have chosen to disclaim responsibility and fail to take adequate precautions against the known and specific danger posed by fake drugs in the market. Undoubtedly, given their substantial financial resources, manufacturers and large distributors have the best knowledge of the dangers of drug distribution. They are also in the best position to identify “the precautions that are necessary to safely perform the job.” This “top-down” approach to vicarious liability therefore ensures that those manufacturers and authorized distributors who unscrupulously barter for the lowest-cost drugs without taking precautions to ensure drug integrity and safety do not escape liability.

To protect themselves against this vicarious liability and to satisfy their nondelegable duty of care, manufacturers and distributors need only take the special safety precautions readily available to them. Numerous safety precautions exist to keep counterfeit, adulterated and diverted drugs out of the legitimate stream of commerce. First, manufacturers and distributors could merely acquiesce to a pedigree requirement, either electronic or paper, that began with the manufacturer and exempted no party from the

---

119 Wilson, 757 F.2d at 1306.
120 Instead fighting a reasonable federal pedigree requirement for nearly 20 years and only engaging in brief forays in the last two years in “track and trace” technology that might record the distribution of drugs. Drug Tracing Heats Up, Sec. Mgmt., May 2007, at 18-19.
121 Id. at 1301.
122 Although I do sit on the Advisory Board for Secure Symbology, this article does not advocate that any one of the listed options for improving the security of the drug supply should be mandatory or preferred by the courts, the FDA or Congress. Companies should exercise their autonomy and select the safety procedure that meets their own corporate needs so long as it adequately safeguards patients’ health.
requirement. Many technologies (including lower cost solutions such as bar coding, covert, encoded inks) and higher-cost solutions such as Radio Frequency Identification Technology (RFID) and DNA-embedding technologies are now available that the drug industry can implement to “trace and trace” the source and distribution of medication and produce electronic pedigrees. A multi-pronged, layered-use of

---

123 This would stand in contrast to the current requirements of 21 Code of Federal Regulations Section 203.50 which, if enforced, would still exempt manufacturers and all authorized distributors from a pedigree requirement. See supra at Section III(A).

124 Secure Symbology provides unique, multi-dimensional bar codes that help track a drug to the point of sale for use on individual units of drugs, cases of drugs, pallets of drugs and larger containers of drugs. Describing one of its product, the ESC System, the company states that:

Secure Symbology Inc.’s ESC System provides “track and trace” reliability from production to pharmacist, assuring consumer protection, while meeting the stringent compliance requirements of federal and state regulatory agencies. It accomplishes this by using globally accepted machine-readable bar code symbologies, and/or the emerging RFID technology, within the context of SSI’s patented and novel utilization of construction, deconstruction and reconstruction of databases.


126 In its most common of terms, RFID can be defined as a generic term for technologies that use radio waves to automatically identify people or objects. There are several methods of identification, but the most common is to store a serial number that identifies a person or object, and perhaps other information, on a microchip that is attached to an antenna (the chip and the antenna together are called an RFID transponder or an RFID tag). The antenna enables the chip to transmit the identification information to a reader. The reader converts the radio waves reflected back from the RFID tag into digital information that can then be passed on to computers that can make use of it.


127 Applied DNA Sciences offers markers for implementation which uniquely identify a real product from a counterfeit. Describing its patented SigNature markers, the company stated that:

SigNatureDNA Markers, we use DNA segments from one or more botanical sources, rearrange them into unique encrypted sequences, and then implement one or more layers of anti-counterfeit techniques. Because the portion of DNA in a SigNature DNA Marker used to identify the marker is so minute, it cannot be detected unless it is replicated billions of times over, or amplified. This amplification can only be achieved by applying matching strands of DNA, or a primer, and PCR techniques to the SigNature DNA Marker. The sequence of the relevant DNA in a SigNature DNA Marker must be known in order to manufacture the primer for that DNA.


128 Electronic Pedigrees can be produced once a manufacturer or distributor employs a tracker, such as a bar code or RFID, a data management base and a communications mechanism to relay information to partners. VeriSign, Supply Chain Information Center, http://www.verisign.com/global-consulting/supply-chain-services/supply-chain-information/drug-pedigrees.html. (last visited June 17, 2007). VeriSign markets an Electronic Pedigree Service that it states can manage these three components efficiently. Id.
multiple technologies and a mandatory pedigree requirement (without exempt parties) would provide the most security.\textsuperscript{129}

Manufacturers and distributors are well-aware of these technologies. The pharmaceutical companies even choose to dabble in technology pilot projects.\textsuperscript{130} Nonetheless, those same parties have failed to use any of the technologies in a widespread manner. Even the FDA, however, has scolded drug manufacturers and distributors for not implementing readily-available technological advances.\textsuperscript{131}

SupplyScape sells a computer software application, Supplyscape E-pedigree, which works in conjunction with other technology to produce pedigree papers electronically, cutting down the cost and amount of human hours necessary to provide source documentation for drugs. SupplyScape, E-Pedigree Overview, http://www.supplyscape.com/products/pedigree/index.html (last visited June 17, 2007).

\textsuperscript{129} Purdue Pharma’s model for tracking Oxycontin provides a useful model for tracing drugs, Purdue Pharma’s system consists of ultrahigh-frequency (UHF) tags and readers, device management software, and data management software (Class 0 UHF tags and readers, Symbol Technologies, Holtsville, NY; device-management software, Northern Apex Software, Fort Wayne, IN; “Auto-ID” and “Event Manager” software from SAP AG, Walldorf, Germany). This system interacts with the company's enterprise resource-planning system ("R/3 ERP," SAP AG) and makes it possible to link each bottle of OxyContin to a specific case and pallet.


\textsuperscript{131} Despite the promise of technology, pharma’s use of RFID today remains limited to a handful of test projects. An FDA report this month, while calling those efforts encouraging, chastises drugmakers, wholesalers, and retailers for being slow to implement “e-pedigree” systems such as bar codes or RFID to prevent drug counterfeiting. The report singled out RFID adoption in particular: “We are disappointed with the lack of overall progress across the drug supply chain.” Time for the pharmaceutical industry to pick up the pace, amid a growing number of FDA and state government mandates for drug pedigree systems.
The risk of counterfeit drugs reaching patients has long surpassed a mere possibility. In the wake of that reality, wholesalers still resist pedigree laws, and manufacturers continue to view wholesale distributors as their primary concern and consumers rather than worrying about the safety of patients. Therefore, patients should begin suing manufacturers and all distributors for the injury caused by counterfeit drugs until the drug industry satisfies its nondelegable duty of care in distribution by implementing technological security measures and acquiescing to the full implementation of pedigrees. The drug manufacturers and distributors can satisfy their obligation to protect the public and cut off liability by merely implementing the special precautions that exist.

The drug industry is unique and well-suited for the application of the peculiar risk doctrine. No other industry serves a population who, already compromised by some health condition, is so vulnerable. The dangers posed by counterfeit drugs range from death by poisoning, at the worst, to the ingestion of non-active ingredients by sick consumers who will deteriorate without proper medical dosing, which can lead to a patient’s decline, illness and potential death as well. Additionally, the inter-relationship of manufacturers, who hold patents to these medicines which make them the unique suppliers of a medicine or a group of medicines, and the distributors who serve them calls for a special liability standard.

---


132 See supra pp. 1–3.


134 After I testified to the Senate Judiciary Committee in opposition of amending Florida’s pedigree definition in 2006, a representative from Astra Zeneca said that although she understood my concern about drug integrity, the manufacturer could not publicly oppose the will of the distributors who wanted to water down the pedigree as “the distributors were [their] consumers.”
Beyond the existing vicarious liability of manufacturers and distributors for counterfeit drugs outlined above, another approach to secure the drug supply chain would be for Congress to enact legislation imposing strict liability on manufacturers and all distributors for injuries caused by counterfeit drugs. Given their concern for the endangerment of health, environmental laws imposing strict liability for injury caused by the distribution of hazardous chemical byproducts of legitimate industry provide a strong analogy for Congress to act and create strict liability for injury caused by the distribution of counterfeit drugs, harmful chemicals which are the “social byproduct” of the legitimate drug industry.

A. Strict Liability for Injury Caused by the Distribution of Harmful Chemical Byproducts

RCRA governs the treatment, handling and disposal of solid and hazardous waste. The purpose of RCRA was to “. . . empower[] [the] FDA to regulate hazardous

\[\text{\footnotesize{\textsuperscript{135}} RCRA allows private citizens to bring suit against past of present generator, operator or owner who has contributed or is contributing to the handling, storage, treatment, transportation or disposal of waste which may present an imminent and substantial endangerment to health or the environment, 42 U.S.C. § 6972(a)(1)(B) (2000); the EPA Administrator can bring similar suits when health is endangered as well under RCRA, Id. § 6973(a). CERCLA also focuses on the threat to public health as the trigger for action including when the President may abate activity which poses such a threat: “when the President determines that there may be an imminent and substantial endangerment to the public health or welfare or the environment because of an actual or threatened release of a hazardous substance from a facility, he may require the Attorney General of the United States to secure such relief as may be necessary to abate such danger or threat. “ Id. § 9606(a).\]


30
wastes from cradle to grave, in accordance with . . . rigorous safeguards. . . “  

137 RCRA is largely a “forward looking” statute in that most of its provisions attempted to create a regulatory scheme for the future storage, treatment, transport and disposal of waste.  

In addition to promulgating a pro-active regulatory scheme, however, RCRA establishes strict liability for past or present generators, transporters, operators of treatment or owners of waste whose handling of waste may present an imminent and substantial endangerment to health or to the environment.  

139 RCRA gives both the government and private citizens the right to seek judicial relief to avert imminent and substantial threats to the public health.  

140 RCRA allows the EPA or a private citizen to obtain an injunction when any person is so presenting an endangerment to the public health.  

141 Congress intended RCRA, as initially enacted and then as later amended in 1984, to impose strict liability without reference to fault or negligence.  

Orders Under Section 7003 of the Resource Conservation and Recovery Act,” which was issued by the E.P.A. on September 26, 1984), available at http://www.epa.gov/compliance/resources/policies/cleanup/rcra/971020.pdf. This article presumes that counterfeit, adulterated, or diverted medicine is hazardous to human health because it does not, at the very least, meet FDA requirements for human consumption in its most innocuous form.  

137 Envil. Def. Fund, 511 U.S. at 331.  


139 The E.P.A. would bring suit on these grounds under 42 United States Code 6973, which private citizens would bring such a strict liability suit under section 6972. See SUSAN M. COOKE, THE LAW OF HAZARDOUS WASTE: MANAGEMENT, CLEANUP, LIABILITY AND LITIGATION § 15.01(3)(a) (2005) (stating that “liability under Sections 7003 and 7002(a)(1)(B) [is applicable] to any person who (1) has contributed or is contributed to (2) the past or present handling, storage, treatment, transportation, or disposal of (e) any solid or hazardous waste which (4) presents an imminent and substantial endangerment to health or the environment”).  


141 Bliss, 667 F. Supp. at 1313.  

142 United States v. Ne. Pharm. & Chem. Co., 810 F.2d 726, 740 (8th Cir. 1986) (holding that CERCLA applied retroactively and that RCRA imposed strict liability upon past off-site generators and transporters of hazardous substances). RCRA imposes liability without fault or negligence and applies to present conditions resulting from the past activities of past off-site generators and transporters. Bliss, 667 F. Supp. at 1313. Also, Congressional discussion of the standard “regardless of fault or negligence” and the statement that “non-negligent generators whose waste are no longer being deposited at a particular site may be ordered to abate the hazard to health or the environment posed by the leaking of the waste they once generated and which have been deposited at the site.” Cooke, supra note 139, at § 15.019(4) (citing H.R. Rep. No. 198, pt. 1, at 47–49 (1983), as reprinted in 1984 U.S.C.C.A.N. 5576, 5606–09).
CERCLA is “backwards looking,” as the provisions are not regulatory in nature and instead focus on creating broad civil liability for cleanup of leaking sites of waste treatment, transport, storage and disposal.\textsuperscript{143} CERCLA provides that the United States, a State or a private citizen may bring actions to recover costs incurred in responding to releases of hazardous substances.\textsuperscript{144} CERCLA joins RCRA in imposing strict liability without regard to a liable party’s fault or state of mind.\textsuperscript{145} Responsible parties may be jointly and severally liable, although liability may also be apportioned among defendants in appropriate cases.\textsuperscript{146} The intent of including a strict liability standard in CERCLA and not allowing parties to contract out of that liability was to ensure that economic might did not allow manufacturers to use economic power to shift liability for harm onto those who transported, distributed or treated the hazardous material.\textsuperscript{148}

\begin{itemize}
\item \textsuperscript{143} FINDLEY & FARBER, \textit{supra} note 138, at 121.
\item \textsuperscript{144} COOKE, \textit{supra} note 139, at § 14.01[1].
\item \textsuperscript{145} Bliss, 667 F. Supp. at 1313 (holding the generators of waste and the company that arranged for the transportation of the waste and the company, which store and sprayed oil on the container of waste, were all jointly and severally liable for the expense of the government’s cleanup of dioxin and TCP to abate the release of hazardous substances); \textit{contra}, e.g., United States v. A & F Materials Co., 578 F. Supp. 1249, 1258 (S.D. Ill. 1984) (holding that Congress intended courts to apply the equities of each case when apportioning fault amongst defendants).
\item \textsuperscript{146} A & F Materials Co, 578 F. Supp. at 1256 (noting that Congress intended courts to follow a moderate approach to joint and several liability under CERCLA); COOKE, \textit{supra} note 139, at § 14.01[2][c].
\item \textsuperscript{147} In United States v. Price, the court noted that, the strict liability standard fits most closely with the legislative aims of CERCLA which include goals such as cost-spreading and assurance that responsible parties bear their cost of the clean up. H.R.Rep. No. 1016, \textit{supra} at 17, reprinted in U.S.Code Cong. & Ad.News at 6119; see 68 U.Va.L.Rev. 1157 (1982). The fulfillment of these Congressional goals is more likely to be effectuated if the defendants who allegedly contributed to the environmental mess are now held to a very stringent standard of liability. Though strict liability may impose harsh results on certain defendants, it is the most equitable solution in view of the alternative-forcing those who bear no responsibility for causing the damage, the taxpayers, to shoulder the full cost of the clean up. 577 F. Supp. 1103, 1114 (D.C.N.J. 1983) (citation omitted).
\item \textsuperscript{148} With Senator Randolph concurring, Senator Cannon discussed why Section 107(e)(1) was enacted, stating: It is my understanding that this section is designed to eliminate situations where the owner or operator of a facility sees its economic power to force the transfer of its liability to other persons, as a cost of doing business, thus escaping liability under the act all together. 126 CONG. REC. 30,984 (1980), \textit{reprinted in} I CERCLA, LEGISLATIVE HISTORY OF THE COMPREHENSIVE ENVIRONMENTAL RESPONSE, COMPENSATION, AND LIABILITY ACT, 1980, at 22, 308 (1980). In discussing both the Senate and the House’s three key concerns with hazardous substance legislation, Representative Florio stated that the “absence of negligence is not a defense to liability,” as CERCLA would create a
\end{itemize}
Using the same rationale of the necessity of protecting health or the environment that motivated Congress to enact strict liability in both RCRA and CERCLA, Congress could enact strict liability for manufacturers and distributors when counterfeit drugs pass through the legitimate distribution system and injure patients. Certainly, the hazardous waste contemplated by the environmental statutes and fake medicine are all chemical compounds. Manufacturers of pharmaceutical drugs are similar to the generators of industry who when making their legitimate and valuable products produce hazardous chemical by-products. In the context of generators, the chemical product is the hazardous waste itself. For manufacturers of pharmaceuticals, the dramatic high prices of their medicine that they set create the “social byproduct” of counterfeit drugs as criminals pollute the drug stream trying to profit from the very demand and price created by pharmaceutical manufacturers. As Congress did not allow generators of hazardous waste use their economic might to contract out of liability for hazards later caused by the disposal of hazardous waste, so too would Congress act justifiably to hold manufacturers responsible for injury caused by counterfeit drugs rather than allowing them to escape liability through their hiring of distributors.

Further, drug distributors should also be held jointly and severally liable under a strict liability for injuries caused by counterfeit drugs as those distributors are similar to the “transporters” of hazardous waste covered by the environmental statutes.149 Drug distributors select the sources of medicine from which they buy and can choose to buy only from the manufacturers and not from other avenues which open the door for

---

criminals to penetrate the drug supply. Instead, distributors try to increase their profits by engaging in pharmaceutical arbitrage, trying to buy medicines at costs lower than even the manufacturers of those drugs offer.\textsuperscript{150} Like transporters who continually haul waste to a landfill which was contaminated,\textsuperscript{151} distributors have continuously bought bad drugs from cheap suppliers, thereby reaping millions of dollars and perilously endangering lives. Also, distributors choose not to employ new security measures such as bar coding or RFID, which makes their inventory susceptible to penetration by criminals if even only one unscrupulous employee of a distributor allows a felon to introduce counterfeit drugs into its warehouse.\textsuperscript{152}

A federal statute holding drug manufacturers and distributors jointly and severally liable could provide for both a government directed suit and a private citizen suit. Following RCRA’s equitable remedy model, when the FDA through its own investigation or through the investigation of state pharmaceutical agencies discovers that counterfeit drugs have been released into the legitimate drug supply, the statute could enable the FDA Commissioner or a private citizen to seek an injunction directing the manufacturer of the drug and all distributors to remove the entire lot number or a series of lot numbers of the drug from the marketplace. Additionally, following the CERCLA paradigm of seeking “clean up costs,” a federal statute could enable the FDA to recoup the costs of investigation and prosecution relating to a counterfeit medicine and allow a

\textsuperscript{150} See discussion of authorized distributors’ purchase practices \textit{supra} pp. 5–7.
\textsuperscript{151} United States v. Waste Indus., 556 F. Supp. 1301 (E.D.N.C. 1982) (denying a motion by transporters for summary judgment in a RCRA action because “the extent of the use by the haulers [of the contaminated site] was sufficient to avoid summary judgment on their behalf”).
\textsuperscript{152} Neil Spence, a single employee at Cardinal Health, enabled felon Michael Carlowe to sell thousands of dollars worth of counterfeit drugs into the distributor which in turn sent the drugs out nationally to retailers. United States v. Spence, Carlow, No. 3:06-00047 (M.D. Tenn. 2006).
private citizen to recoup any medical costs or other personal injury damages she or he has had to incur due to the ingestion of fake medicine.

**B. Defining an Imminent and Substantial Endangerment to Health**

Of critical importance to any proposed federal drug statute would be defining the trigger event of when counterfeit, adulterated or diverted medicine presents an imminent and substantial endangerment to health. RCRA’s provisions allow the EPA or a private citizen to seek injunctive relief when hazardous waste “may present” an imminent and substantial endangerment to the environment. The inclusion of the terms “may present” signifies Congress’ intent to provide courts with broad equitable powers to abate any risk posed by toxic wastes. However, RCA does not allow the EPA or a private citizen to enjoin hazardous waste activity when “the risk of harm is remote in time, completely speculative in nature or de minimus in degree.

What constitutes an imminent and substantial endangerment under RCRA is an inherently fact-specific question. The Supreme Court noted that an endangerment is “imminent” if it threatens to occur immediately, and the term implies that the danger be a present threat, “although the impact of the threat may not be felt until later.” This “lenient standard” allows government intervention to prevent hazardous waste

---

153 42 U.S.C. Sections 6972(a)(1)(B) and 6973(a) authorize suit against those who handle hazardous waste in a manner which “may present an imminent and substantial endangerment to health or the environment.”
154 Cooke, supra note 139, at § 15.01(3)(e) (citing United States v. Waste Indus., Inc., 734 F.2d 159, 166 (4th Cir. 1984); United States v. Price, 688 F.2d 204, 231 (3d Cir. 1982); United States v. Valentine, 856 F. Supp. 621 (D. Wyo. 1994)).
156 Cooke, supra note 139, at § 15.01(3)(e) (noting that the standard has not been thoroughly explored by the courts). The difficulties of interpreting this statutorily undefined standard with contemplated by my colleague, Joel A. Mintz. See Joel A. Mintz, Abandoned Hazardous Waste Sites and the RCRA Imminent Hazard Provision: Some Suggestions for a Sound Judicial Construction, 11 HARV. ENVTL. L. REV. 247 (1987).
158 Price, 688 F.2d at 211.
contamination from happening, although the latent harm to public health caused by the contamination might not be evident for a long period of time. Imminence must be construed in consideration of the time it takes for administrative and judicial action, including the preparation, issuance and enforcement of administrative court orders, to achieve the legislative purpose of protecting public health.

CERCLA does not define what constitutes an “imminent and substantial” risk to public health within its own provisions. Actual harm need not have occurred before the government or a can seek relief. A threatened or potential harm is sufficient to qualify as an endangerment. Under CERCLA, “a finding of endangerment requires the Court to evaluate the nature and degree of the risk posed by the hazardous substances.”

For the proposed federal statute, Congress could implement the same standard to trigger strict liability that Congress wrote into RCRA and CERCLA: circumstances which may present an imminent and substantial endangerment to health. In FDA Guidance memoranda the Agency could propose a list of non-exclusive factual scenarios which would highly circumstances when an individual or the government would know that counterfeit drugs “may present” such an endangerment to public health, although no actual harm to health has yet occurred. During the course of federal or state investigations, the discovery of counterfeit, adulterated or diverted medicine should be a

159 Id.; Cox v. Dallas, 256 F.3d 281, 299 (5th Cir. 2001).
161 United States v. Conservation Chemical Co. 619 F. Supp. 162, 192 (W. Dist. Mo. 1985) The court laments that Congress gave no guidance as to the specifics of the factual circumstances that would constitute such a danger under CERCLA. Id.
162 Id. at 193 (“Because endangerment entails only a threat of harm, the endangerment provisions ‘have enhanced the courts traditional equitable powers by authorizing the issuance of injunctions when there is but a risk of harm, a more lenient standard than a traditional requirement of threatened irreparable harm’”) .
sufficient trigger for the government or an individual to seek injunctive relief to abate future harm to consumers. When counterfeit drug labels are found, this too presents facts which should trigger liability and action because of the endangerment to public health. Finally, when breaches of security at either manufacturing or distributing facilities are uncovered, again, the FDA or a citizen should have the power to ask the court to issue a recall of that tainted drug by issuing injunctive relief.

Certainly, a patient suffering actual harm from counterfeit drugs would satisfy the imminent and substantial endangerment standard. At that point, using CERCLA as the “clean up” model, a federal statute should allow the patient to recoup her or his personal injury damages and allow the FDA to recover the costs of conducting a recall of the drugs pursuant to a court-issued injunction.

**Conclusion**

The FDA’s Anti-Counterfeiting Task Force reports and state experiences with the outbreak of drug counterfeiting, contaminating and diverting demonstrate the risk posed to the public by tainted drugs. The use of independent contractors or the economic might of manufacturers and authorized distributors is no longer an adequate justification for exempting them from liability for injuries caused by these tainted products. Either or the two paradigms of liability suggested by this article, (1) judicial imposition of vicarious liability because of manufacturers’ and authorized distributors’ nondelegable duty of safe distribution or (2) Congressional action to impose strict liability when tainted

---

165 The government or an individual should be able to seek an injunction forcing the manufactures and distributors of the identified drug to recall all units of the identified drug which bear the same lot number as the bad drug.
166 Discovery could happen due to law enforcement or private citizen whistleblowers.
167 See supra Part I.
168 See supra Parts I.–III.B.
drugs may present an imminent and substantial endangerment to health following
environmental laws’ commitment to protecting health, would enhance patient safety.
Buying drugs from a multiplicity of sources because of low prices and failing to take
adequate precautions in this industry of peculiar risk should no longer be economical for
corporations. The liability system should favor protecting innocent, dependent patients
over protecting any corporate profit margin. Mahatma Ghandi best articulated the need
for the prioritization of the public’s well-being over monetary gain: “[i]t is health that is
real wealth and not pieces of gold and silver.”169

169 Mem’l Hosp. v. Maricopa County, 415 U.S. 250, 259 n.14 (quoting President Nixon’s use of Ghandi’s
1971)).