

Trojan Drugs: Counterfeit and Mislabeled Pharmaceuticals in the Legitimate Market

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I. INTRODUCTION

Over the past five years, there have been over 140 reported incidents of counterfeit and mislabeled drugs being sold by legitimate pharmacies in the United States.¹ Thousands of patients have consumed these medications, sometimes with dire consequences.² The extent of counterfeits in the legitimate market, however, is unknown. It is certain that the detected incidents of fakes are a fraction of the total number of incidents.³

How did these drugs wind up in the bloodstreams of unsuspecting patients? Despite elaborate safety precautions, strict regulations and battalions of enforcement personnel, the stream of phony pharmaceuticals continues unabated. This article will consider the practical and legal dimensions of trade in Trojan drugs.⁴

This paper will *not* consider the two major sources of counterfeit medications in the U.S. – direct importation and internet pharmacies. These routes are the subject of numerous scholarly articles⁵ and the field is so vast that they deserve separate

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¹ From 2000 to 2004, there have been 142 counterfeit drug cases opened by the FDA. A few of these involved Internet “pharmacies”, however, which are not considered in this article. Food and Drug Administration, *Combating Counterfeit Drugs: A Report of the Food and Drug Administration Annual Update* (May 18, 2005), <http://www.fda.gov/oc/initiatives/counterfeit/update2005.html> (last visited Oct. 18, 2005).

² KATHERINE EBAN, DANGEROUS DOSES: HOW COUNTERFEITERS ARE CONTAMINATING AMERICA’S DRUG SUPPLY (2005) [hereinafter EBAN].

³ *Id.* at 334-336.

⁴ I use the term “Trojan Drugs” advisedly. This is not (yet) a term of art.

⁵ See JODY FEDER, CONGRESSIONAL RESEARCH SERVICE REPORT FOR CONGRESS, PRESCRIPTION DRUG IMPORTATION AND INTERNET SALES: A LEGAL OVERVIEW, Order Code RL32191 (Jan. 8, 2004), [available at http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RL32191.pdf](http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RL32191.pdf) (last visited Feb. 27, 2006). See also The Partnership for Safe Medicine, *Safety Resources*, <http://www.safemedicines.org/safety/> (last visited Feb. 27, 2006), including articles by the FDA, the American Pharmacists Association, the National Association of Chain Drug Stores, Medline Plus, and the National Consumers’ League; regarding internet pharmacies. See e.g., Susan Coburn, *A Web Bazaar Turns Into a Pharmaceutical Free-For-All* (October 25, 2000),

consideration. It is difficult to consider Trojan Drugs without some reference to these sources, but the reader is cautioned that the treatment of these topics in this paper is necessarily cursory.

II. THE CARLOW CASE

Michael Carlow is a scoundrel. The twice-convicted felon⁶ had a penchant for the good life as defined by the standards of South Florida. After his release from prison, Carlow embarked on a new career as a pharmaceutical wholesaler. Over a five-year period, he amassed a fortune of many millions, purchased a mansion in Weston, FL, owned a garage full of exotic automobiles, and spent weekends on his yacht.⁷ Pretty good for a down-and-out loser from Ohio.

Carlow had stumbled into one of the most lucrative criminal enterprises in America: drug counterfeiting. During his brief career, Carlow literally poisoned hundreds of desperately ill patients, caused drug companies millions in losses, and damaged the reputations of some of the best-known pharmacies in the country. How did he get away with it for so long? More importantly, how many of his ilk are practicing this trade today, undetected by any watchdogs of the nation's drug supply? The Carlow case is a study of the ease with which criminals can exploit the gaps in the regulatory regime governing America's drug distribution network.

Carlow started his career in the black market with brute force, stealing large quantities of pharmaceutical drugs from distributors, and then selling the goods back to the victim.⁸ Even when employing this tactic, however, he was careful to set up a front company to accomplish the resale, so the transaction had a patina of legitimacy.⁹ This method, however, was soon replaced with more sophisticated techniques.

- Medicaid Fraud: Carlow discovered that hundreds of HIV/AIDS patients were getting free medications under the Medicaid program in South Florida.¹⁰ These pharmaceuticals could be extremely expensive. Carlow also recognized that many of the patients had other habits, such as drug addiction. Carlow offered these unfortunates cash for their prescriptions,

<http://www.nytimes.com/library/tech/00/10/biztech/technology/25cobu.html> (last visited Sept. 15, 2005).

⁶ Before starting a career as a drug counterfeiter, Michael Carlow was sentenced for armed robbery of a business (1973), for grand theft (1984), selling cocaine (1986) and in 2000 was convicted of buying AIDS and cancer drugs from the trunk of a car at a Miami intersection. See EBAN, *supra* note 2, at 60-61; DONALD DEKIEFFER, EDDI, INC, INDIVIDUAL REPORT ON MICHAEL ALLYN CARLOW [hereinafter CARLOW REPORT]. EDDI, Inc. is a specialist in identifying potential product diverters, counterfeiters, money launderers and other forms of commercial fraud. See EDDI, Inc., <http://www.eddi-inc.com> (last visited Feb. 27, 2006).

⁷ CARLOW REPORT; EBAN, *supra* note 2, at 56-60.

⁸ See EBAN, *supra* note 2, at 94-100, 200-203 for a fairly complete analysis and description of the Carlow operation.

⁹ Carlow at one point had more than 15 front companies registered in several states. See CARLOW REPORT, *supra* note 6 and EBAN, *supra* note 2, at xv-xi, 44-48, 61-64, 68-69, 95-96, 129, 202, 222-223, 284-285.

¹⁰ EBAN, *supra* note 2, at 92-97; Sally Kestin and Bob La Mendola, *Former Convicts Try a Safer Venture: Pharmaceuticals*, SUN SENTINEL, May 26, 2003, available at <http://www.hhs.gov/importtaskforce/session2/presentations/newsArticlesOnCounterfeiters.doc> (last visited Oct. 20, 2005); SUPREME COURT OF FLORIDA, CASE NO: SC02-2645, SECOND INTERIM REPORT OF THE SEVENTEENTH STATEWIDE GRAND JURY, REPORT ON RECIPIENT FRAUD IN FLORIDA'S MEDICAID PROGRAM (Dec. 2003), <http://myfloridalegal.com/interimjury17.pdf> (last visited Feb. 27, 2006).

which they could then use for heroin and crack cocaine. Of course, he paid only pennies on the dollar for their vials of injectables. He then laundered these drugs through a series of shell companies, and resold the medications into the legitimate wholesale chain.¹¹

- Relabeling: Carlow, through an elaborate chain of phony companies located around the country, procured low-dose versions of popular oncology medications, counterfeited higher-dose labels for these goods, and resold the now more valuable merchandise to second-tier wholesalers in Florida and six other states.¹²
- Diversion: The Carlow family of companies located offshore sources for U.S.-made drugs, reimported the medications, and sold them to unquestioning dealers. In some cases, the goods were relabeled to conform to U.S. standards.¹³

Over the years, Mr. Carlow and his associates moved into wide-scale counterfeiting of such products as Lipitor.¹⁴ His confederates notoriously operated warehouses for drug distribution in the back rooms of strip clubs, much like Tony Soprano at the Bada Bing.¹⁵

At its height, the Carlow Group operated more than two dozen front companies in a half-dozen states. The Group's revenues exceeded \$3 million per month.¹⁶ It is one thing to steal or to fraudulently acquire bogus (or relabeled) medication; quite another to be paid handsomely for it by legitimate dealers. How did Carlow pull this off?

The Carlow case illustrates the weaknesses in the pharmaceutical distribution chain in the United States. Although many of these infirmities exist in other industries, there are few which offer so many opportunities for fraud as prescription medications.

III. DRUG DISTRIBUTION IN THE U.S.

Unlike most industry sectors, pharmaceutical distribution in the United States is almost wholly beyond the control of manufacturers. Even the most heavily-regulated drugs pass through a distribution chain which is Byzantine in its complexity. Many of the largest pharmaceutical companies have only a handful of customers, including major wholesalers, government agencies, and extremely large users. Once the goods leave their loading docks, manufacturers have little concept of how and where their products are ultimately dispensed.

The three major wholesalers in the country — AmerisourceBergen,¹⁷ Cardinal Health¹⁸ and McKesson¹⁹ — handle over 80% of the drugs sold.²⁰ Government

¹¹ EBAN, *supra* note 2, at 92-97.

¹² *Id.*

¹³ *Id.*

¹⁴ Lipitor is a trademark of Pfizer Co. It is a cholesterol-lowering medication (atorvastatin calcium). Liptor (atorvastatin calcium) Cholesterol Medication, <http://www.lipitor.com> (last visited Feb. 27, 2006).

¹⁵ At least some of the drugs handled by the Carlow ring were distributed from the Playpen South, a strip club in Fort Lauderdale, FL. See EBAN, *supra* note 2, at 195-201.

¹⁶ CARLOW REPORT, *supra* note 6; EBAN, *supra* note 2, at 269, 271; Sally Kestin and Bob LaMendola, *Florida Agents Bust Large Pharmaceutical Counterfeiting Ring*, SUN-SENTINEL, July 22, 2003, available at 2003 WLNR 12447012.

¹⁷ Amerisource Bergen Corporation (NYSE: ABC) has over 14,000 employees, and annual sales of around \$50 billion. Amerisource Bergen, Investor Relations,

agencies, such as the Veterans Administration,²¹ and secondary wholesalers handle the remaining 20 percent.²² Exported drugs, which do not generally pass through these routes, constitute another tributary in the distribution stream which is similarly opaque to the manufacturers.²³

The major wholesalers stock thousands of drugs from hundreds of manufacturers. They procure almost all of their stock directly from producers, and sell to most pharmacies around the country. The operative words in the prior sentence are “almost” and “most”. Until recently²⁴ all of the “majors” have purchased a portion of their stock from secondary wholesalers rather than manufacturers. These secondary wholesalers sometimes buy their drugs from the manufacturers, but often acquire pharmaceuticals from other sources. These sources include:

- “Short-dated” lots from pharmacies (or other health-care providers) which need to move merchandise before their expiration date
- Exotic medications such as antivenins which the “majors” do not want because volume is so low

<http://www.amerisourcebergen.com/investor/phoenix.zhtml?c=61181&p=irol-irhome> (last visited Feb. 27, 2006).

¹⁸ Cardinal Health (NYSE: CAH) of Dublin, Ohio has annual sales in excess of \$65 billion.

¹⁹ McKesson Corporation (NYSE:MCK) with headquarters in San Francisco, is the largest of the “big three” distributors. It has sales over \$80 billion.

²⁰ U.S. Food and Drug Administration, *FDA’s Counterfeit Drug Task Force Interim Report* (October 2003), http://www.fda.gov/oc/initiatives/counterfeit/report/interim_report.html (last visited Sept. 14, 2005) [hereinafter *Interim Report*]; EBAN, *supra* note 2, at 90; Joshua Walker, Forrester Research, Inc., *Can RFID Help Pharma’s Drug Distribution Problem?* (March 12, 2004), http://www.cyclonecommerce.com/media/pdfs/rfid_in_pharma.pdf (last visited Feb. 27, 2006).

²¹ Alliance for Health Reform, *Covering Health Issues, Appendix D – Department of Veterans Affairs*, <http://www.allhealth.org/sourcebook2004/pdfs/appendixd.pdf> (last visited Sept. 14, 2005); United States General Accounting Office, *Major Management Challenges and Program Risks: Department of Veterans Affairs, Performance and Accountability Series* at 19 (January 2003), <http://www.gao.gov/pas/2003/d03110.pdf>.

²² For purposes of this article, the term “secondary wholesalers” means any licensed wholesaler except the “big three” a discussed above. In the industry, many people refer to “tertiary wholesalers” to describe those companies which are on the very margins of legitimacy, such as most of the Carlow entities. The distinction between secondary and tertiary wholesalers, however, is indistinct.

²³ See HOUSE COMM. ON ENERGY & COMMERCE, SUBCOMM. ON OVERSIGHT & INVESTIGATIONS, 99TH CONG. 2D SESS., UNCERTAIN RETURNS: THE MULTIMILLION DOLLAR MARKET IN REIMPORTED PHARMACEUTICALS __ (Comm. Print 99-GG 1986). See also *Ortho Pharmaceutical Corp. and Johnson & Johnson (Hong Kong) Ltd. v. Sona Distributors, Inc. and Elmcrest Trading, Ltd.*, 663 F. Supp. 64 (S.D.Fla. 1987); Final Rule Announcing Procedures and Requirements to Implement PDMA, 64 Fed. Reg. 67720, 67729 (Dec. 3, 1999) (discussing the comment that “a large proportion of the ‘export’ drugs that are diverted never actually leave the United States”); American Society of Consultant Pharmacists, Policy Statement on Reimportation of Prescription Drugs (approved July 29, 2002), at <http://www.ascp.com/public/pr/policy/reimportation/>.

²⁴ In May, 2005, Cardinal Health announced that it would stop purchasing from the secondary market:

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 wholesale competitors as part of a high-profile investigation of drug sourcing, counterfeiting and the pharmaceutical supply chain.

James Frederick, *Cardinal latest wholesaler to curb secondary dealing*, DRUG STORE NEWS, May 23, 2005, at 8, available at 2005 WLNR 8725663.

- Bulk-packaged goods which they repackage in smaller bottles etc. for better commercial utility
- Reimported drugs
- Other wholesalers²⁵

The primary reason the “majors” buy even a small portion of their inventory from the secondary market is price.²⁶ Because the secondary wholesalers would have no price advantage over their larger customers if they were procuring drugs from the same place, they compete by knowing when and where to buy discounted product.

The major distributors operate at very thin profit margins, rarely exceeding 5 percent.²⁷ If, however, they can purchase inventory at 10% or more below the price offered by the manufacturer, the result goes directly to the bottom line. This has traditionally been too tempting to resist for even the most ethical of companies. The secondary wholesalers, after all, are governed by the same regulatory regime as the majors, so what’s the harm in making a buck or two at the expense of the manufacturers?

Unfortunately, these secondary market sales are the primary, if not exclusive means by which Trojan drugs enter the bloodstreams of the unwary.

IV. GOVERNMENT REGULATION OF PHARMACEUTICAL DISTRIBUTION

Like the distribution network itself, the regulation of pharmaceutical products in the United States is labyrinthic.

At the Federal level, at least three government agencies, the Federal Trade Commission (FTC), the Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA), have nominal jurisdiction over great swaths of the pharmaceutical industry and its components. Other regulators, ranging from the

²⁵ The secondary pharmaceutical market is a “behind-the-scenes” venue in which wholesalers purchase and sell medications to each other “outside the normal drug-manufacturing channel.” Stephanie Saul, *Subpoenas Seek Data On Resale of Drugs*, N.Y. TIMES, Apr. 9, 2005, at C1. Medications on the market come from a number of sources, including manufacturer overstocks and wholesalers who have purchased too much product and want to resell it. *Id.* The drugs also come from pharmacy benefit managers, hospitals and mail-order pharmacies that receive preferential pricing on products and then want to resell excess supplies, according to Sandy Greco, vice president of pharmaceutical distributor Kinray. *Id.* While many such sources are legitimate, foreign markets -- from which the drugs are stolen and then resold in the United States -- and counterfeiters, who make fraudulent medications to sell to wholesalers, also provide drugs to the secondary market. *Id.*

²⁶ EBAN, *supra* note 2, at 91, 373 (note to page 91, stating that in October 2003, a person associated with Cardinal showed the author a document from the Cardinal trading company listing the amounts saved by making purchases from alternative secondary distributors). *See also*, First Interim Report of the Seventeenth Statewide Grand Jury, Supreme Court of Florida, Case No: SC02-2645, at 7 (2003) [hereinafter First Interim Report], <http://myfloridalegal.com/pages.nsf/4492D797DC0BD92F85256CB80055FB97/09558F82389E020785256CDA006DB01A?OpenDocument>; FDA, *Profile of the Prescription Drug Wholesaling Industry: Examination of Entities Defining Supply and Demand in Drug Distribution*, Final Report (Feb. 12, 2001) at 1.3 [hereinafter final report]; EASTERN RESEARCH GROUP, INC., PROFILE OF THE PRESCRIPTION DRUG WHOLESALING INDUSTRY § 1.3 (2001), *available at* <http://www.fda.gov/oc/pdma/report2001/>; Bruce W. Hamilton, Letter to Anthony L. Young Re: Impact of New PDMA Rules on the Pharmaceutical Distributor Markets (Oct. 26, 2000)(attached to Testimony of Anthony L. Young on Behalf of the Pharmaceutical Distributors Association, Public Hearing on Regulations Implementing the PDMA, Oct. 27, 2000, *available at* <http://www.fda.gov/ohrms/dockets/dailys/00/oct00/103000/103000.htm>).

²⁷ *Cf* Melissa Davis, *Gray Clouds Imperil Drug Firms*, TheStreet.com, *at* http://www.thestreet.com/stocks/melissadavid/10240816_2.html (Sept. 6, 2005).

Veteran's Administration to the Agriculture Department establish policies in niches carved out of the overall regime.²⁸ In all, more than twenty Federal agencies have developed controls of one sort or another over pharmaceutical products.²⁹

Even the lead agencies have confusing and overlapping jurisdiction.

The DEA, for example, enforces many of the country's drug laws. While their primary concern is for narcotics such as cocaine and heroin, they also enforce statutes involving prescription medications such as Oxycontin®, and even over-the-counter cold medications such as Sudafed®.³⁰

The FDA is nominally in charge of regulating prescription medications. It does so through elaborate qualification procedures for new drugs, and strict controls over the production of approved medications. Its jurisdiction also extends to enforcement of drug distribution channels for approved Rx drugs.³¹

The FTC is concerned with "all other" consumer products which might be misrepresented in the marketplace, such as claims that herbal nostrums are safe and effective.³² Added to this bouillabaisse of authority are more than two score Federal police agencies.³³

The states, however, retain authority over some of the most important components of the drug distribution chain: wholesalers, retailers and physicians. State Boards of Pharmacy regulate (on paper at least) who may participate in drug distribution within their borders. These regulations vary widely, as does the actual enforcement of the law. It is perfectly legal in Florida, for example, for a convicted felon's wife to operate a pharmaceutical wholesale operation, hiring her husband as

²⁸ See e.g. 38 U.S.C. § 8126 (2005) (discussing Veteran's Administration regulations on the procurement and supply of prescription drugs); Final Rule for Pharmaceutical and Industrial Production on Plants Genetically Engineered to Produce Industrial Compounds, 70 Fed. Reg. 23009 (May 4, 2005); Field Testing of Plants Engineered to Produce Pharmaceutical and Industrial Compounds, 68 Fed. Reg. 11337 (March 10, 2003); Industry Guidance on Drugs, Biologics, and Medical Devices Derived From Bioengineered Plants for Use in Humans and Animals, 67 Fed. Reg. 57828 (Sept. 12, 2002); Dep't of Agric. Policies on Regulation of Biotechnology, 51 Fed. Reg. 23302, 23303 (June 26, 1986); U.S. GEN. ACCOUNTING OFFICE, GAO-03-110, PERFORMANCE AND ACCOUNTABILITY SERIES: MAJOR MANAGEMENT CHALLENGES AND PROGRAM RISKS; DEPARTMENT OF VETERANS AFFAIRS 19 (January 2003), available at <http://www.gao.gov/pas/2003/> (last visited Mar. 2, 2006); ALLIANCE FOR HEALTH REFORM, COVERING HEALTH ISSUES Appendix D (2004), available at <http://www.allhealth.org/sourcebook2004/toc.asp>.

²⁹ Departments and agencies such as the Department of Defense have their own requirements for packaging and coding of pharmaceuticals.

³⁰ For a complete list of substances controlled by the DEA, see http://www.deadiversion.usdoj.gov/schedules/listby_sched/sched2.htm.

³¹ The Center for Drug Evaluation and Research (CDER) has oversight responsibilities for prescription, over-the-counter and generic drugs. CDER, Frequently Asked Questions to CDER, Question No. 2, "What drugs are regulated by CDER?," at <http://www.fda.gov/cder/about/faq/default.htm#2> (last modified Sept. 19, 2002).

"This responsibility includes products, such as fluoride toothpaste, dandruff shampoos and sunscreens. CDER evaluates the benefits and risks of drugs, and oversees the research, development, manufacture and marketing of drugs. CDER ensures truth in advertising for prescription drugs and monitors the use of marketed drugs for unexpected health risks. If unexpected risks are detected after approval, CDER takes action to inform the public, change a drug's label, or--if necessary--remove a product from the market." *Id.*

³² The basic "consumer protection" statute enforced by the Commission states, *inter alia*, that "unfair or deceptive acts or practices in or affecting commerce are...declared unlawful." FTCA, 15 U.S.C. §45(a)(1)(2005). "Unfair" practices are defined to mean those that "cause or [are] likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition." 15 U.S.C. § 45(n).

³³ These include *inter alia*, the Coast Guard, FBI, Customs (CBP and ICE), and numerous department-specific police.

a “consultant.”³⁴ This was one of the scams Mr. Carlow employed to evade scrutiny in the Sunshine State. Similarly, the laxity of laws in some states makes them a honey pot for unscrupulous wheeler-dealers. Until 2002, for example, Nevada was well-known as a souk for scam artists in the wholesale drug trade.³⁵

At the state level, actual enforcement of these laws is even more problematic than among the various Federal agencies. Most Boards of Pharmacy lack police power, and employ only a handful of inspectors.³⁶ To arrest malefactors, they must look to traditional law enforcement, which is generally ill-equipped to *understand* the issues involved, much less undertake vigorous investigations.

To compound the problem, cooperation between state and Federal authorities in this field is fraught with difficulty, the parties fighting each other over jurisdictional turf as often as apprehending malefactors.³⁷

Finally, U.S. Attorney’s offices around the country, which are charged with actually prosecuting crimes committed by pharmaceutical bandits, are ill-equipped for the mission. These cases tend to be complex and, as a result, present a significant drain on resources. Many U.S. Attorneys remain reluctant to prosecute these cases in all but the most egregious circumstances, preferring to handle the less complicated villainy which abounds in most metropolitan areas.

V. MIXED SIGNALS

If the institutional problems of maintaining a comprehensible system of pharmaceutical regulations were not enough, politicians have further complicated the issue. For the past several years, Members of Congress,³⁸ State Governors³⁹ and even mayors⁴⁰ have urged that existing barriers to importation of pharmaceuticals be loosened or abandoned altogether. The Prescription Drug Marketing Act (PDMA) is the primary source of these restrictions.⁴¹

³⁴ As in the Michael Carlow case, *see* EBAN, *supra* note 2, at 45, 58, 64, 92-93; Carlow Report, *supra* note 6; *See also* First Interim Report, *supra* note 26, generally.

³⁵ EBAN, *supra* note 2, at 320-328 (recounting Nevada’s battle for control of its prescription drug supply).

³⁶ In 2003, the Washington Post published a series of investigative articles dealing with drug diversion and counterfeiting; one of these contained an especially critical analysis of the state of enforcement. Gilbert M. Gaul & Mary Pat Flaherty, *U.S. Prescription Drug System Under Attack: Multibillion-Dollar Shadow Market Is Growing Stronger*, WASH. POST, Oct. 19, 2003, at A1 (hereinafter “Gaul & Flaherty”), *available at* <http://www.washingtonpost.com/ac2/wp-dyn/A44908-2003Oct18>. It noted in passing, “Nationwide, there are an estimated 6,500 small wholesalers, yet most states have only a handful of inspectors. In some states, amusement park rides, elevators and even dog kennels are inspected more frequently than drug wholesalers.” *Id.*

³⁷ *E.g.* EBAN, *supra* note 2, at 28, 106, 108-109, 174-178.

³⁸ Congressmen Rahm Emanuel (D-Illinois), Gil Gutknecht, (R-Minn), and Senators Byron Dorgan (D- ND), John McCain (R- AZ), and Edward Kennedy (D-MA) have been particularly vociferous in this regard.

³⁹ Governors Tim Pawlenty (MN), Rod R. Blagojevich (IL), Craig Benson (NH), Jim Doyle (WI), Brad Henry (OK) and John Hoeven (ND) have been outspoken in their support of increased drug imports, especially from Canada.

⁴⁰ Springfield, Massachusetts mayor Michael Albano became the first to import Canadian drugs, closely followed by several others. In 2003, for example, Boston mayor Thomas M. Menino said that he was looking into buying Canadian prescription drugs for Boston city workers and would “very seriously” consider flouting the Food and Drug Administration ban on imports if it was not lifted. Christopher Rowland, *Menino Eyes Drug-Import Plan Mayor Say He’d Consider Flouting FDA to Cut Costs*, BOSTON GLOBE, Oct. 29, 2003, at F1, *available at* 2003 WLNR 3440595.

⁴¹ The PDMA is incorporated into the FDCA, and proscribes a variety of conduct set forth in the FDCA’s “prohibited acts” section at 21 U.S.C. § 331(t)(2005). The penalties for these offenses are set forth at 21 U.S.C. §333(a) and (b). The PDMA, which was signed by the President on April 22,

The motivation for removing barriers is purportedly to reduce prescription drug costs by permitting liberal importation of medications from countries which offer considerably lower prices. Proponents of this position argue that the PDMA protects artificially high drug prices in the U.S., and raises costs to health care providers and governments alike. They also point out that the favored “alternative source” for importing drugs would be Canada, which has a record comparable to that of the U.S. in detecting counterfeits.⁴²

The FDA has repeatedly testified that even with the PDMA in place, they are unable to verify the authenticity or safety of drugs which are currently entering the country.⁴³ They assert that if the PDMA restrictions were withdrawn, the country would be flooded with unapproved and potentially hazardous medications.

Given the inability of the FDA to even *monitor* illicit drugs entering the U.S. in violation of the PDMA, some solons have suggested that changing the law would merely make *de jure* that which is already *de facto*.⁴⁴ The pharmaceutical industry demurs, largely because most of the current imports appear to be for personal use, and comprise a minor source for the legitimate U.S. retail market. They fear repeal of the PDMA would subject them to wholesale competition from abroad.⁴⁵

Notwithstanding the merits (or lack thereof) of the various arguments on this matter, it is clear that imported pharmaceuticals are a major source of counterfeits

1988, was enacted to ensure that prescription drug products purchased by consumers would be safe and effective and to avoid an unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs were being sold to the American public. FDA, PRESCRIPTION DRUG MARKETING ACT: REPORT TO CONGRESS, Executive Summary 4 (June 2001), available at <http://www.fda.gov/oc/pdma/report2001/default.htm>. Congress decided that legislation was necessary because there were insufficient safeguards in the prescription drug distribution system to prevent the introduction and retail sale of substandard, ineffective, or counterfeit drugs and that a wholesale drug diversion submarket had developed that prevented effective control over, or even routine knowledge of, the true sources of drugs. *Id.*

⁴² See Joel Lexchin, *Drug withdrawals from the Canadian market for safety reasons, 1963–2004*, 172 CAN. MED. ASS’N J. 765 (2005) (but questioning the adequacy of Canadian statistics on drug withdrawals), available at <http://www.cmaj.ca/cgi/content/full/172/6/765/>.

⁴³ The FDA’s own website notes, “A growing number of Americans obtain their medications from foreign locations, often seeking out suppliers in Canada. But FDA cannot ensure the safety of drugs bought from these sources.” FDA, Importing Prescription Drugs, at <http://www.fda.gov/importeddrugs/> (last visited Mar. 2, 2006).

⁴⁴ See e.g. Aidan Hollis and Aslam Anis, *Rx for Canada: Close the Internet Pharmacies*, 205 C. D. HOWE INSTITUTE COMMENTARY 1 (2004), available at <http://www.cdhowe.org/english/publications/currentpubs.html>. The authors (both Canadian) argue that Internet pharmacies are a threat to Canadian drug prices, and that both Canadian consumers and the drug companies will benefit by closing them down. *Id.*

In Manitoba, located just across the border from North Dakota, 1,500 people are employed by Internet pharmacies that cater to hundreds of thousands of US residents. Jesse C. Vivian, B.S. Pharm., J.D., *Canadian Drug Imports*, U.S. PHARMACIST (July 15, 2003), available at http://www.uspharmacist.com/index.asp?show=article&page=8_1113.htm.

“One Manitoba pharmacy estimates that 90% of its business comes from US prescriptions. According to the Manitoba Pharmaceutical Association, the number of Internet pharmacies in Manitoba that mail prescription drugs to Americans has risen to 51 from 30 since January 1, 2003. Many of these Canadian pharmacies deal in more than 1,000 medications and fill as many as 2,000 drug orders a day, and each order typically contains a three-month supply. Canadian pharmacists claim that Americans can save as much as 80% by buying prescription drugs in Canada, thanks to government price controls and the relatively weak Canadian dollar.” *Id.*

⁴⁵ The argument of the pharmaceutical industry is not as crass as this, of course. They argue that amending the PDMA to permit drug importation would also import foreign government price controls into the U.S. “These price controls stifle the much needed innovations that create new and better medicines. Rather than turning to foreign government price fixing, Congress should enhance access to needed medicines by completing work on a market-based Medicare prescription drug benefit.” See the PhRMA websites at <http://www.phrma.org>.

finding their way to legitimate pharmacy shelves in the U.S. The very existence of a debate over importation policy creates additional uncertainty in the market, and, ironically, gives questionable wholesalers a convenient argument for their activities, viz: “I did it for Granny.”⁴⁶ This leaves open one of the widest doors for counterfeits to enter the U.S. marketplace.

VI. THE DIVERSION PIPELINE

As noted *supra*, there have been threescore cases of counterfeit drugs being discovered in the U.S. over the past 5 years. In *every single case* the bogus medicaments were “piggybacked” on apparently “legitimate” shipments of gray market goods.⁴⁷ Some of these, as in the Carlow case, were manufactured in the U.S. In other instances, however, the counterfeits were acquired abroad.

The international drug distribution chain is at once more straightforward and more complex than even the bizarre U.S. system. Outside the U.S., government agencies or international organizations procure most drugs.⁴⁸ In other cases, although the actual purchase and distribution of drugs may be in private hands, governments strictly control prices and terms of sale.⁴⁹ This results in various “price points” around the globe where the same medication may be sold at prices a fraction below those prevailing in the U.S., or almost given away to needy patients.⁵⁰ These disparities create a magnet for arbitrageurs.

Arbitrage is a respected mechanism for setting world prices for commodities such as oil and cotton. It is easily adaptable, however, and can be as readily applied to dog food or pharmaceuticals as it is to iron ore. “Arbs” look for price disparities around the world for the same product, buy that item in a low-cost country and resell it where it can command a higher price. The Arbs take a bit of the spread for themselves, of course. When significant price disparities exist, as they do with pharmaceuticals, Arbs become ravenous. They aggressively seek supplies of low-cost merchandise for resale at just below wholesale prices in higher-cost markets. The spreads in these cases can be enormous – often topping 100%. This can be a bonanza for Arbs familiar with working commodities where spreads are in the 4-9% range.

⁴⁶ Letter from James R. Office, Vice President and General Counsel, Victory Wholesale Grocers, to Donald S. Clark, Secretary, Federal Trade Commission (May 20, 2004), *available at* <http://www.ftc.gov/os/comments/rfid-workshop/508920-0001.pdf>. In commenting upon proposed FTC rules implementing Radio Frequency Identification (RFID) of packaging for food and drugs, Victory Wholesale Grocers (an admitted diverter) noted, “Victory’s presence in the marketplace increases competition, improves overall market efficiency and uniformity, and benefits retailers and consumers through access to lower priced goods”.

⁴⁷ FDA’s Counterfeit Drug Task Force Interim Report (Oct. 2003), *available at* http://www.fda.gov/oc/initiatives/counterfeit/report/interim_report.html (last accessed Sept. 14, 2005).

⁴⁸ *See, e.g.*, PAN AMERICAN WORLD HEALTH ORGANIZATION, ANTIRETROVIRAL PRICES AGREED IN THE NEGOTIATIONS OF THE 10 LATIN AMERICAN COUNTRIES (June 2003), *available at* <http://www.paho.org/English/AD/FCH/AI/negociaciones-arv-la-25.pdf>. (last accessed Sept. 15, 2004). *See also* WHO MEMBERSTATES AND MEDICINES PRICE INFORMATION, *available at* http://www.who.int/medicines/areas/access/ecofin_who_memberstates/en/index.html.

⁴⁹ *E.g.*, Australia, Canada, Norway, Sweden and the United Kingdom.

⁵⁰ *See e.g.*, MÉDECINS SANS FRONTIÈRES, UNTANGLING THE WEB OF PRICE REDUCTIONS: A PRICING GUIDE FOR THE PURCHASE OF ARVs FOR DEVELOPING COUNTRIES (8th ed. June 28, 2005), *available at* <http://www.accessmed-msf.org/prod/publications.asp?sentid=28620051846504&contenttype=PARA&> (last accessed Sept. 15, 2005).

Sellers in arbitrage deals, of course, demand their own markup from their procurement cost. While this reduces the arbitrage spread, there is plenty of slack in the market for several people to take a cut and become wealthy to boot. Some sellers, however, are even greedier. They substitute even *lower* cost counterfeits for the legitimate products, thus boosting their profits, while increasing their attractiveness to the Arbs.

On the buyer's side of an arbitrage deal, purchasers receive what appear to be a legitimate product at something below the wholesale prices offered by the original manufacturer. Often, this margin is rather small, but in the multibillion dollar drug market, even a 2% savings on a \$1 million transaction translates to \$20,000 which can be made with a few phone calls. Good work if you can find it.

The buyers expect that they are receiving the legitimate product, although they usually realize that it has been diverted from its intended market. The buyer is blissfully unaware whether the seller has clandestinely substituted counterfeits or salted fakes among the good products in the shipment. Buyers, who are mostly secondary or tertiary wholesalers, then offer the goods to the three majors (*supra*) who pass it along to retailers and ultimately to consumers.

VII. SOURCES OF DIVERTED DRUGS

A. INTERNATIONAL DIVERSION

Sales or outright gifts of expensive medications such as HIV/AIDS drugs are particularly vulnerable to this sort of manipulation. There is a huge demand for these drugs in developing countries, and they can be extremely expensive. Further, there is enormous political pressure on the pharmaceutical companies to make these products available to the poor. Whether eleemosynary motivations or self-defense persuades the manufacturers to provide these goods to Africa, for example, matters not to the Arbs. They offer instant profits to anyone who can acquire the goods for resale in the West. Even in the best-managed systems such as South Africa, almost 50% of these products shipped to Africa never find their way into the bloodstreams of the indigenous population.⁵¹ The balance is shipped to Western Europe and the U.S. where they are sold through back channels into the legitimate market.⁵²

A similar danger lies in transfers of pharmaceuticals to even the best-run international aid organizations. In some cases, the Non-Governmental Organizations ("NGOs") may employ deficient accounting procedures, and in others, more seemingly benign reasons may cause drugs to be diverted. For example, NGOs are sometimes overwhelmed by donations of health-care products. This often occurs in

⁵¹ See Matthew Chapman, *Trade in Aids Drugs*, BBC NEWS, April 24, 2005, available at http://news.bbc.co.uk/2/hi/uk_news/4476329.stm (last accessed Sept. 16, 2005).

⁵² Sarah Boseley & Rory Carroll, *Profiteers resell Africa's cheap Aids drugs*, GUARDIAN UNLIMITED, Oct. 4, 2002, available at <http://www.guardian.co.uk/aids/story/0,7369,804387,00.html>. "At least \$18m (£12m) worth of Combivir and other highly effective antiretroviral drugs made by the British company GlaxoSmithKline is believed to have been hijacked. The drugs were to be sold at significantly discounted prices to clinics in Senegal, Ivory Coast, the Republic of Congo, Togo and Guinea-Bissau under a scheme to offer some drugs at lower prices to poor countries agreed by Glaxo and four other drug companies with the World Health Organization. But about 3m doses of Combivir - a third of the supply - was diverted back to Europe by profiteering wholesalers as it arrived at the African airports or even earlier. 'There are indications that perhaps some of these batches never even left Europe,' said Alan Chandler, a Glaxo spokesman."

the immediate aftermath of disasters.⁵³ In these cases, NGOs sometimes sell or barter surplus relief supplies to acquire items that better meet the needs of the afflicted. The buyers of these surplus items routinely transship them to the gray market.

To avoid this, some of the most famous aid organizations such as Oxfam routinely refuse donations of products, but request financial assistance from the outset.⁵⁴ Others, however are not so scrupulous. Even United Nations organizations have been found to be the source for drugs entering the diversion market.⁵⁵

Third World bureaucracies are also notorious for their corruption. It is routine for employees of Health Ministries in Africa and elsewhere to act as middlemen in complex diversion plots. In these cases, government-run clinics place seemingly legitimate supply orders with pharmaceutical manufacturers. Of course, the orders specify substantial discounts from Western prices. Interestingly, the orders sometimes also require delivery in packaging which is identical to those available in the country of origin. This raises questions with suppliers, who sometimes attempt to thwart diversion by shipping the products in distinctive export packaging. To parry such inquiries, the fraudsters adopt a variety of excuses, ranging from the plausible to the comical. E.g.:

“We lack sufficient resources for drug testing, and want assurances these products meet U.S. standards”;

“Our doctors are all trained in the U.S. (or Western Europe) and are only familiar with drugs available there”.

“Our local consumers are so sophisticated they will eschew any product not made in the U.S.”

U.S. packaging makes the products substantially easier to sell in the gray market which is often the real reason for the “Western Packaging Only” requirement.

B. DOMESTIC DIVERSION

In addition to international diversion, numerous conduits exist in the U.S. for pharmaceuticals to exit – and re-enter—the legitimate distribution pipeline:

1. Closed-Door Pharmacies

There are thousands of so-called “closed door” or “own use” pharmacies in the United States. These include nursing homes, hospitals, rehabilitation clinics and

⁵³ For a description of the problem and further references, see <http://web.worldbank.org/WBSITE/EXTERNAL/TOPICS/EXTHEALTHNUTRITIONANDPOPULATION/EXTHSD/0,,contentMDK:20188673~menuPK:438756~pagePK:148956~piPK:216618~theSitePK:376793,00.html>

⁵⁴ See THE WORLD BANK, *Counterfeiting, Diversion, Corruption*, at <http://web.worldbank.org/WBSITE/EXTERNAL/TOPICS/EXTHEALTHNUTRITIONANDPOPULATION/EXTHSD/0,,contentMDK:20188673~menuPK:438756~pagePK:148956~piPK:216618~theSitePK:376793,00.html>. (Gives a description of the problem and further references).

⁵⁵ The Economist, *A line in the sand*, THE Economist, Sept. 16, 2000. During the U.N. interventions in Liberia and Sierra Leone in the early 1990s, for example, peacekeepers were accused of looting, trafficking in diamonds, selling arms to rebel militias, and committing wholesale human rights abuses. By 1997, more than 10,000 Nigerian troops had been deployed in and around Freetown, Sierra Leone’s capital. The peacekeepers were accused of selling munitions and drugs to rival factions and mined diamonds alongside them. In 2000, the Commander of the United Nations force in Sierra Leone (UNAMSIL), Vijay Jetley, charged the Nigerians with sabotaging peace in the country and duplicity in prolonging the conflicts in West Africa for personal gain.

many other facilities wherein the proprietors have agreed not to provide medications to retail customers, but only to their own, “captive” clientele. These entities are permitted to acquire pharmaceuticals at prices which are far below Wholesale Average Prices (“WAC”).⁵⁶ This results, of course, in a tiered pricing system which is a major source of fraud. For example, a nursing home chain may claim that it needs sufficient medications to serve a population of 800 beds. The pharma companies (and their agents) have very good projections as to the volume and variety of drugs which would be needed to service this account. They generally keep extremely good records of which medications are ordered, and are able to respond fairly quickly in the event that a closed door facility departs too much from the expected norm. The accuracy of the supply model, of course, is based upon the assumption that the patient population reported by the customer is accurate.

In some cases, however, sophisticated crooks have “invented” patient populations through a variety of schemes, all to justify purchases of large quantities of expensive drugs at a discount. Numerous methods have been employed to accomplish this scam, including the establishment of interlocking corporations so that the same beds can be double or even triple-counted in the event of a physical audit.⁵⁷ The profits to be made from the sale of the below-WAC pharmaceuticals by closed-door pharmacies is so enormous, it has attracted organized crime figures.⁵⁸

In most cases, the closed-door pharmacy scam may also subject the perpetrators to liability for Medicare or Medicaid fraud,⁵⁹ but an operator who is not too greedy (e.g. by not claiming Medicaid reimbursement *in addition to* the profits on the diverted drugs) can escape detection for years.⁶⁰

2. Samples

One of the most common marketing techniques used by pharmaceutical companies to promote their products is by providing free samples to physicians for their patients.⁶¹ This opens at least two major sources for diversion.

Sales representatives sometimes do not deliver the full amount of samples intended for their physician accounts. They then sell the surplus into the gray market.⁶² This is often done in collusion with the physicians who receive a kickback from the illicit profits.⁶³

In other cases, the physicians themselves serve as the sole source of the diverted drugs. Although the pharmaceutical manufacturers have elaborate policies intended to detect outright theft (or non-delivery) of merchandise to doctors, these procedures

⁵⁶ See e.g., EBAN, *supra* note 2, at 90-91; Gaul, *supra* note 36; NATIONAL ASSOCIATION OF BOARDS OF PHARMACY, TASK FORCE ON DRUG DIVERSION THROUGH INSTITUTIONAL OUTLETS (2000), *available at* http://www.nabp.net/ftpfiles/task_force_reports/Task_Force_on_Drug_Diversion_through_Institutional_Outlets.doc (last accessed Oct. 20, 2005).

⁵⁷ Gaul & Flaherty, *supra* note 36. The case of David Dyck is summarized.

⁵⁸ See *id.*

⁵⁹ See *First Interim Report*, *supra* note 26.

⁶⁰ See Gaul & Flaherty, *supra* note 36. The case of Marty Rubin is summarized.

⁶¹ DAVE ESCALANTE, ACHIEVING EFFICIENCY THROUGH OUTSOURCED SAMPLE MANAGEMENT (Product Management Today 2004). “Delivering a sample product to a physician is a pharmaceutical company’s single most important promotional activity for increasing product awareness and utilization, growing market share and revenue.”

⁶² See, e.g. REPORTS U.S. ATTORNEY, *Six Additional TAP Employees Charged with Conspiracy and Kickback Crimes*, PR NEWSWIRE, July 16, 2002.

⁶³ *Id.*

are sometimes short-circuited by collusive behavior by sales reps and the doctors they are directed to service.⁶⁴

3. “In House” Schemes

One of the least discussed methods by which pharmaceuticals enter the diversion market is through connivance of employees. These schemes take many forms, and are extremely difficult to detect since the perpetrators are necessarily familiar with every aspect of the drug distribution chain and the security measures designed to frustrate drug diversion. Further, most drug companies place enormous trust in their employees, and design policies intended to combat illicit trade in their products while still making a profit. The plots are as diverse as imagination can fathom.

One of the major problems in this arena is the penchant for manufacturers to measure sales employees’ performance by the amount of product that they manage to sell. This measure, as intuitive as it might be, creates perverse motivations within the sales force. Sales representatives are rewarded or punished “by the numbers”, that is, they must achieve certain sales goals if they expect to keep their jobs or be rewarded for superior performance. Despite company rules against diversion, the imperative to sell is often an absolute, trumping even the most unambiguous anti-diversion policies.

As noted above, it is impossible in a brief article to describe all of the ingenious schemes which have been used by employees to “pump their numbers” or to acquire drugs for their private resale, but a few examples are illustrative.

In several cases, sales reps took advantage of disparities among regulations concerning the prices at which states were willing to reimburse sellers (or doctors) for certain medications under their Medicare and Medicaid programs. Some states set very low price schedules, while others were much more generous. Seeing an opportunity for arbitrage, while simultaneously increasing their apparent sales, some salesmen persuaded doctors in “below WAC” states to order significantly more inventory than they could possibly use. The sales reps then arranged for the resale of these products to higher-reimbursement states. The profits from this scheme were shared with the cooperating physicians. In this case, doctors in *both* the high-cost and low-cost states were in cahoots with the employees, and made substantial profits over several years. This artifice did not result in any greater *overall* sales of drugs by the manufacturer, but did deprive the company of sales in the high-reimbursement states, since much of the market had already been filled by the gray market goods. The plot also deprived other sales reps of their “numbers” while making the schemers appear to be sales geniuses.⁶⁵

Other schemes have involved “take backs” of allegedly damaged goods which were, in fact, entirely viable. The purchaser received a credit from the manufacturer, and split profits from the ultimate sale of the “damaged” goods with the inside conspirator.⁶⁶

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ See e.g., Jamie Herzlick, *LI Firm Execs Face Charges; Ex-chairman, others arrested*, *Newsday*, Aug. 13, 2003. This sort of scheme was perfected by Allou Distributors of Brentwood, NY in the early 1990s. Allou, which has since gone bankrupt, was one of the major diversion “facilitators” in the U.S. until it collapsed in 2003. Prosecutors unraveled numerous schemes including insurance fraud, money laundering and even arson.

These exemplars demonstrate not only the ingenuity of corrupt employees, but the real vulnerability of manufacturers to unethical activities. Unfortunately, it is impossible to quantify the volume of employee-induced diversion since except in the most egregious cases, these incidents go unreported. Even when detected, the corporate response is often to quietly discipline the perpetrators rather than publicly acknowledge systemic problems.

4. Theft

As seen in the Carlow case *supra*, outright theft of pharmaceuticals is a significant source for the diversion market. Although pilferage from pharmacies is a major problem, large-scale burglaries and even cargo hijackings are not uncommon.⁶⁷ Local law enforcement authorities are often sensitive to theft of controlled substances such as opioids, but are often less alert to the implications of purloined prescription medications. In most cases, people who steal pharmaceuticals *other than* controlled substances sell their swag in the gray market. These individuals are generally well-prepared. They know precisely where they can fence their goods, the going market prices, and the terms of sale for their booty. Usually the buyers are tertiary wholesalers, but sometimes, they are able to sell the medications directly to independent pharmacies.⁶⁸

5. Doctor Shopping and Pill Mills

As strict as the regulatory regime may appear on paper, it is only as efficient as the ultimate arbiters of who may receive medications – and in what amounts. “Doctor Shopping” is a method used extensively by addicts to acquire controlled substances – especially pain medications.⁶⁸ A prospective patient will visit numerous physicians seeking prescriptions for such products as Oxycontin ®. These patients can often obtain multiple prescriptions in a single day. In some cases, they will discover a doctor who is extremely generous in prescribing huge quantities of medications.⁶⁹ Since many pharmacies are alert to this scheme, they routinely notify physicians if the same patient attempts to have multiple scripts filled in a short period. To thwart this, doctor shoppers and other alert scam artists locate “pill mills” i.e. pharmacies which will not ask too many questions about the medical needs of their customers.

While the majority of doctor shoppers and pill mills cater to those who actually use drugs (including black-market street sales of the goods), a significant minority of cases involve other prescription medications ranging from birth control pills to oncology medications. These understandably attract less attention from law

⁶⁷ The National Association of Drug Diversion Investigators (NADDI) offers on-line reports of current pharmaceutical hijackings, burglaries, thefts and other forms of drug diversion. NADDI Home Page, www.naddi.org (last visited Mar. 2, 2006).

⁶⁸ See e.g., John Burke, NADDI, *Drug Diversion: The Scope of the Problem* at 4, available at <http://www.naddi.org/publications/scope.pdf> (last accessed Sept. 20, 2005).

⁶⁹ *U.S. v. Hurwitz*, NO. 03-cr-00467 (E.D. VA filed Sept. 25, 2003, judgment April 21, 2005) (William E. Hurwitz sentenced to 25 years imprisonment and fined \$ 1 million for conviction on 50 counts of illegal drug distribution, including conspiracy to distribute controlled substances and charges related to drug trafficking that resulted in one death and serious bodily injury to others). See also *Hurwitz v. Bd. of Medicine*, 46 Va. Cir. Ct. 119 (1998) (denying Hurwitz’s petition challenging the decision of the Virginia Board of Medicine, which exercised its summary suspension power on the ground that the doctor’s unprofessional conduct in inadequate history-taking, and referrals to other professionals, coupled with an apparent unquestioning compliance with patients’ requests for prescriptions and refills, justified board intervention).

enforcement than do club drugs, and permit buyers to acquire vast amounts of product without detection. One of the problems with this sort of acquisition, however, is that it does not provide the profit margins available from other methods of getting gray market product. In most cases, the conspirators are paying near-retail for their goods. For this reason, many fraudsters who specialize in non-controlled medications employ guises which enable them to get the goods at subsidized prices – especially through Medicaid fraud.⁷⁰

6. Institutional Purchases

Government institutions such as prisons, VA hospitals, student health clinics and the military receive substantial discounts for their purchases of medications. In most cases, they use wholesalers as suppliers, rather than acquiring the pharmaceuticals directly from manufacturers. State institutions routinely put such acquisitions up for open bid.⁷¹ Under these circumstances, all manner of fraud flourishes.

In some instances, the supplier will fulfill the contract to the government agency, but inflate the contract requirements to *its* supplier, thus receiving a surplus (at discounted prices) which it can divert to the gray market.⁷²

Theft and misappropriation of inventory is also a major cause for shrinkage in government institutions, and is less routinely detected than in for-profit organizations. Even when it is, government procurement rules and civil service protections often thwart effective and timely responses to the problem.⁷³

⁷⁰ See Centers for Medicare and Medicaid Services, *Most Common Medicaid “Rip Offs,”* available at http://new.cms.hhs.gov/FraudAbuseforConsumers/04_Rip_Offs_Schemes.asp#TopOfPage; some of the latest scams have been collected by the Coalition of Wisconsin Aging Groups in *Fraud Alert*, available at <http://www.cwag.org/legal/medicare/index.aspx?ID=112>; Clifford J. Levy and Michael Luo, *New York Medicaid Fraud May Reach Into Billions*, N.Y. TIMES, July 18, 2005, available at <http://www.nysacra.org/nysacra/news/NYMedicaidFraudBillions.htm>; Mark Sherman, Associated Press, *GlaxoSmithKline agrees to pay \$150 million to settle drug price fraud case* (Sept. 20, 2005), available at http://www.boston.com/news/local/massachusetts/articles/2005/09/20/glaxosmithkline_pays_150_million_to_settle_drug_price_probe/?rss_id=Boston+Globe+--+City+Weekly; Melody Peterson, *Bayer Agrees To Pay U.S. \$257 Million in Drug Fraud*, N.Y. Times, April 17, 2003, available at <http://query.nytimes.com/gst/fullpage.html?sec=health&res=9B07E1DD163AF934A25757C0A9659C8B63>.

⁷¹ See, e.g., Guadalupe TX County Commissioners Court, Agenda, December 28, 2004, *Discussion and possible motion to approve an Addendum to Bid No. 05-3910 re: the motion to advertise and open bid specifications for prescription drugs for the Adult Detention Center*; California State Auditor’s Report 2004-406 (Feb. 2004), Special Report to Assembly and Senate Standing/Policy Committees, *State of California: Its Containment of Drug Costs and Management of Medications for Adult Inmates Continue to Require Significant Improvements*, available at <http://bsa.ca.gov/pdfs/reports/2004-406.pdf> (last accessed Oct. 18, 2005).

⁷² In 2001, for example, Dr. Jerome Feldman, 59, billed Medicaid for drugs that patients did not need or in quantities far greater than they needed. Sometimes, he gave them only a fraction of what they needed and diverted the rest. Feldman allegedly sold the excess medicines to wholesale pharmacies in Broward, Palm Beach and Miami-Dade (FL) counties. The firms resold the prescription drugs at sizable profits to legitimate buyers or illegal dealers. Others in the group laundered the money through corporations. *Sun-Sentinel* (Fort Lauderdale, FL) April 20, 2001.

⁷³ In 2005, more than two years after a massive pharmaceutical theft ring was discovered at the Fort Riley, KS Army facility and other government hospitals, the Justice Department is still investigating the matter. The most recent indictments occurred in July, 2005. See Press Release, U.S. Attorney, Dist. of Kan., (July 27, 2005), available at <http://www.usdoj.gov/usao/ks/press/july2005/July27b.html>.

VIII. THE MIDDLE MEN

Once drugs have been acquired by any of the mechanisms described *supra*, they are usually sold to a middle man who arranges for their passage up the chain to larger wholesalers and ultimately consumers. These middle men are often tertiary wholesalers and are frequently licensed by some state authority. Licensing procedures, however, vary widely across the country. In the Carlow case, for example, we have seen how a convicted felon was able to control numerous companies, most of which were duly licensed in a number of jurisdictions.⁷⁴

Even when rules governing licensure are strict, enforcement of the regulations is generally in the hands of a few understaffed employees, often lacking powers of arrest. Further, few states have effective regulations concerning the sources of inventory for these wholesale vendors aside from generalized proscriptions against stolen property.⁷⁵

Con artists, fences and assorted ne'er do wells thrive in this environment. They are prepared to purchase merchandise at the lowest cost possible and to sell it as dearly as possible. Since the major wholesalers want only first-quality product, the tertiary dealers make every effort to render their goods as "clean" as possible – both on paper and in appearance.

Although nominal regulations exist at both the federal and state level regarding the "pedigree" of prescription drugs, these are more illusory than real.⁷⁶ Those

⁷⁴ EBAN, *supra* note 2. Index under "Carlow, Michael," "businesses and shell companies" and chart at 359 "The Epogen Trail to Timothy Fagan."

⁷⁵ See *e.g. id.*, at 179-185, discussing state regulations on pedigree papers in Florida and Nevada. In late 2002 the Florida Supreme Court convened the Seventeenth Statewide Grand Jury to report on Florida's escalating counterfeit drug problem. The Grand Jury's First Interim Report was issued in February 2003 and triggered the passage of new legislation in Florida as well as serving as a model for the FDA in formulating a national strategy to combat counterfeit drugs. See FLORIDA SUPREME COURT, FIRST INTERIM REPORT OF THE SEVENTEENTH STATEWIDE GRAND JURY, Feb. 2003, available at <http://myfloridalegal.com/grandjury17.pdf>; INTERIM REPORT, *supra* note 20, at II.D.2.

⁷⁶ Regarding Federal legislation, Congress enacted the Prescription Drug Marketing Act ("PDMA") in 1988, Pub. L. No. 100-293 (codified as 21 U.S.C. § 353. 21 U.S.C. § 353(e) was amended in 1992 to its present form, Pub. L. No. 102-353.

Each person who is engaged in the wholesale distribution of a drug subject to subsection (b) of this section [prescription drugs] and who is not the manufacturer or an authorized distributor of record of such drug shall, before each wholesale distribution of such drug (including each distribution to an authorized distributor of record or to a retail pharmacy), provide to the person who receives the drug a statement (in such form and containing such information as the Secretary may require) identifying each prior sale, purchase, or trade of such drug (including the date of the transaction and the names and addresses of all parties to the transaction).

On Dec. 3, 1999, the FDA published final regulations in 21 CFR part 203 implementing the provisions of the PDMA as amended. 64 Fed. Reg. 67,720 (Dec. 3, 1999). After publication, the FDA began to receive comments from industry, trade associations and members of Congress objecting to the regulations on the pedigree requirement as well as a petition for a stay of actions supported by entities that would be considered "unauthorized distributors" under the final rule. As a result, the FDA delayed the effective date for the pedigree rules, 21 C.F.R. §§203.3(u) & 203.50, until Oct. 1, 2001, 65 Fed. Reg. 25,639 (May 3, 2000). Since then, the final rule on pedigree papers has been stayed four more times – until Dec. 1, 2006. 66 Fed. Reg. 12,850 (March 1, 2001); 67 Fed. Reg. 6,645 (Feb. 13, 2002); 68 Fed. Reg. 4,912 (Jan. 31, 2003); 69 Fed. Reg. 8,105 (Feb. 23, 2004). For further information see FDA REPORT TO CONGRESS, THE PRESCRIPTION DRUG MARKETING ACT (June 2001), available at <http://www.fda.gov/oc/pdma/report2001/>; see also EBAN, *supra* note 2, at 162-165, 334-339.

Regarding State legislation, the FDA states that all 50 states have enacted some sort of legislation to implement PDMA, *Interim Report*, *supra* note 20, at II. D.2. Following the lead of Florida and Nevada in passing more stringent regulation of wholesale distributor licensing and documentation, however, the FDA has supported the National Association of the Boards of Pharmacy (NABP) in formulating and updating Model Rules for States to adopt regulating wholesale distribution

familiar with the paperwork requirements for tracking the provenance of a particular batch of pharmaceuticals find it laughably easy to evade the restrictions. Falsified documents are routinely used to describe the origin of drugs which have been acquired by theft, fraud, deceit, or other such skulduggery. These documents provide all the “proof” necessary to sell the goods up the chain to the major wholesalers.⁷⁷

The middle men also want their goods to play the part of legitimately-acquired merchandise. To that end, any identifiers on the packaging which would disclose their true provenance are routinely altered or removed.⁷⁸ Sometimes, new packaging is manufactured to resemble the factory product as closely as possible.⁷⁹ The resemblance with original product often ends at this point. Some drugs (especially injectibles) are sensitive to temperature changes. Middle men may make some gestures to maintain a “cold chain,” but this sort of product security is not their strong suit.⁸⁰

Repackers are also an integral part of the journey from the gray market to the pharmacists’ shelves. There are several hundred companies in the U.S. licensed to repackage pharmaceutical products.⁸¹ Unlike most consumer goods, drugs are almost always sold in packaging which was not produced by the maker of the goods therein.⁸² In many cases, the original manufacturer packs goods in institutional-sized bottles containing, for example, 1000 tablets. Repackers empty the original bottle, and sort the tablets into 50-tablet lots, filling smaller bottles with the goods, and re-labeling the new bottles. The original manufacturer is almost always indicated on the label, but additional distributors may be named as well.⁸³ The

of prescription drugs. *Id.* The Model Rules provide for pedigrees in Section 4: Minimum Requirements for the Storage, Handling, Transport, and Shipment of Drugs and Maintenance of Drug Records, Section 5: Security and Anti-Counterfeiting, and Section 10: Recordkeeping. It rejects, however, a requirement for paper pedigrees, which could be implemented immediately. Rather, the NABP recommends that the pedigree provisions come into effect on December 31, 2007 or whenever the technology is available for implementation of electronic pedigrees.

The FDA reports that as of May 2005, four states had laws in place that are similar to the NABP Model Rules (Florida, Nevada, California, and Indiana) and at least two other states are considering adopting the Model Rules (New Jersey and Iowa). *Annual Update, supra* note 1.

⁷⁷ EBAN, *supra* note 2, at 92, 98, 134, 153, 184, 189, 216-217.

⁷⁸ Interim Report, *supra* note 20, at II; *See e.g.*, EBAN, *supra* note 2, at 94 (describing the “pharmaceutical repackaging operation” in Michael Carlow’s laundry room and garage).

⁷⁹ *See, e.g.*, Comparison of authentic packaging to packaging of counterfeit Procrit, ORTHO BIOTECH PRODUCTS, *available at* <http://www.orthobiotech.com/common/counterfeit/PROCRIT/letter.html>; view counterfeit Lipitor packaging, *available at* http://www.pharmacist.com/articles/h_ts_0300.cfm; view counterfeit Serostim, Neupogen, and “Knockoff” from India, *available at* <http://www.fda.gov/oc/initiatives/counterfeit/archive.html> (last accessed Oct. 19, 2005). *See also* EBAN, *supra* note 2, at 154 (low-dose Epogen repackaged as high-dose Epogen).

⁸⁰ EBAN, *supra* note 2, at 87-89.

⁸¹ *See* Final Report, *supra* note 26, at 1.2. As of Jan. 2001, the 28,216 wholesale distributor licenses were current in the 50 States. This figure represents the total number of licenses for wholesale operation; multi-state wholesalers presumably hold licenses in all States where they operate and are required. The total number of licenses does not represent an estimate of the number of unique wholesalers. Packaging and repackaging is a major function of wholesalers, performed by 71% of the license-holders. *Id.*

⁸² Interim Report, *supra* note 20, at II. A & B (showing prominence of repackagers in the U.S. drug distribution center). *See also* Advanced Packaging, Inc. advertisement for pharmaceutical bottling, *at* http://www.advancedpkg.com/pharmaceutical_bottling.html (last accessed Oct. 19, 2005); EBAN, *supra* note 2, at 89.

⁸³ Federal law and regulations assume that packers and distributors might be indicated on prescription drug labels in addition to, or instead of, manufacturers. *See* 21 U.S.C. § 321(g)(2); 21 C.F.R. §201.57(k).

original lot codes are often ink-jetted onto the finished product. This procedure is commercially justified by wholesalers who find it difficult to maintain inventories of huge quantities of medication. It is much easier to sell 10, 50 count bottles than 1 bottle of 500, for example. In other cases, a distributor (or retailer, for that matter) desires private label products which are merely the original goods in new packaging.

As can be imagined, repackers are a godsend to diverters. There is often no need to replicate original packaging to disguise the circuitous route the pharmaceuticals have taken to reach the retailers. Even original goods, purchased directly from the manufacturer are routinely repackaged, so diverted goods are literally indistinguishable from those sold in the normal course of trade. As will be seen, repackaging is also one of the greatest vulnerabilities of the entire drug distribution chain in the case of counterfeits.

The middle men mostly operate in the shadows of the drug industry, but sometimes furtively appear when absolutely necessary. When stiffer pedigree requirements were being considered by the FDA, for example, these companies surfaced to defend themselves against what could have been crippling regulations. They formed an ad hoc organization, the Pharmaceutical Distributors Association (“PDA”), whose members were shrouded in secrecy.⁸⁴ One member was selected as spokesman⁸⁵ who bitterly attacked the proposed rules as unnecessary and burdensome.⁸⁶

IX. THE MAJORS

More than 80% of all the drugs consumed in the U.S. are handled, at one point or another, by one of the three major wholesale distributors, McKesson,⁸⁷ Amerisource Bergen,⁸⁸ and Cardinal Health.⁸⁹ Unlike most consumer products, prescription pharmaceuticals are rarely sold directly from the manufacturer to retailers. The reasons for this are both historical and practical.

⁸⁴ One reason for the secrecy appears to be that the PDA Members intended to disregard the pedigree requirement if passed by Congress. *See, e.g., Regulations Implementing the Prescription Drug Marketing Act, as amended*: Hearings Before the U.S. Department of Health and Human Services, Docket No. 92N-0297 (testimony of Anthony L. Young on Behalf of the Pharmaceutical Distributors Association (stating that small distributors are “keeping their heads down because they fear they will find themselves the subject of an enforcement action if they choose simply to stay in business despite this final rule.”)) (Oct. 26, 2000).

⁸⁵ The list of members of the Pharmaceutical Distributors Association was supplied to the author by the FDA, Department of Health & Human Services, Office of the Commissioner in response to a Freedom of Information Act request (Sept. 15, 2004) submitted by the author to the FDA. The member companies are: Associated Medical Distributors, Inc., Columbia Medical Distributors, AK Medical Supply Co., Inc., Chicago Medical Equipment and Supply, J M Corporation, LAL Consultants Group, JAM Pharmaceutical, High Country Medical, Grand Canyon Medical Enterprises, Expert-Med, Inc., Drugmax, Inc., DIT Healthcare Distribution, Inc., Advance Medical Sales, MC Distributors, MedSource Direct, Michigan RX Brokerage, LLC, National Pharmaceutical, Ltd., PDI Enterprises, Inc., Parke Medical Supply, Priority Pharmaceuticals, Purity Wholesale Grocers, Inc, R & S Sales, LLC, Rx Drug Services, Rebel Distributors Corp., Resource Healthcare Inc., South Pointe Wholesale, Inc., and Wise Choice Health Care.

⁸⁶ Hearings Before the House Committee on Small Business, Subcommittee on Regulatory Reform and Paperwork Reduction (June 8, 2000)(Testimony of Sal Ricciardi, President, Purity Wholesale Grocers, Inc., on behalf of the Pharmaceutical Distributors Association), *available at* http://www.fda.gov/ohrms/dockets/dailys/00/Jul00/072000/c000116_tab0005.pdf.

⁸⁷ For information on McKesson, see McKesson’s website at: <http://www.mckesson.com/company.html>.

⁸⁸ For information on Amerisource Bergen, *see generally* <http://www.amerisourcebergen.com>.

⁸⁹ For information on Cardinal Health *see generally* <http://www.cardinal.com>.

The complex regulatory regime governing drugs has often meant that a single product might go through several channels before it could be legitimately dispensed. For example, pharmacies are required to individually label each filled prescription with their own name, prescribing physician, dosage, and name of the purchaser among other things.⁹⁰ A small pharmacy may handle as many as 800 medications, manufactured by 200 or so companies. The record-keeping for small businesses would be overwhelming but for the wholesalers.

When a pharmacy needs additional stock, it does not need to call the original manufacturer, which may only produce 500-count lots in any event. Rather, it contacts one of the majors with its small order. The major can deliver the product, usually overnight, with all of the documentation necessary.

Even large drugstore chains use the wholesalers to maintain inventory. Since many drugs are time-sensitive, keeping degradable stock on hand can be expensive and the logistics difficult, especially for drugs infrequently used and “orphan” drugs.⁹¹

The majors perform a useful and even necessary function in the supply chain, assuring dependable stocks in a time-efficient manner, and greatly reducing inventory costs for retail pharmacies nationwide. The majors could also be the last, best line of defense against counterfeits were it not for the fact that their own procurement practices are sometimes questionable. Although they procure most of their products directly from the manufacturers, all of the majors have indulged in “spot buys” of branded and generic medications from the secondary market. They do this only when they can purchase the goods at a discount from prices offered by the manufacturers. Although these buys involve a small fraction of their overall requirements, they can account for a substantial portion of their net profits. This is because they rarely pass along the savings to their own customers, using these odd buys to bolster their own bottom lines.

As can be seen from the above, these purchases from the secondary market are often composed of diverted goods. The majors generally commingle the secondary

⁹⁰ Whereas federal law regulates the content and format of labeling for human prescription drugs directed to health care practitioners (21 C.F.R. § 201.57 (2006)), state law regulates the contents of the package or bottle labels of prescription drugs; *see, e.g.*, N.Y. EDUC. LAW §6810 (McKinney 2003), which provides:

Prescriptions. 1. No drug for which a prescription is required by the provisions of the Federal Food, Drug and Cosmetic Act or by the commissioner of health shall be distributed or dispensed to any person except upon a prescription written by a person legally authorized to issue such prescription. Such drug shall be compounded or dispensed by a licensed pharmacist, and no such drug shall be dispensed without affixing to the immediate container in which the drug is sold or dispensed a label bearing the name and address of the owner of the establishment in which it was dispensed, the date compounded, the number of the prescription under which it is recorded in the pharmacist's prescription files, the name of the prescriber, the name and address of the patient, and the directions for the use of the drug by the patient as given upon the prescription.

available at <http://public.leginfo.state.ny.us/menugetf.cgi?COMMONQUERY=LAWS>.

⁹¹ The term “orphan drug” refers to a product that treats a rare disease affecting fewer than 200,000 Americans. Orphan Drug Act, 21 U.S.C. § 360bb (2006), *available at* <http://www.fda.gov/orphan/oda.htm>. In 1983, Congress passed the Orphan Drug Act to support research, development, and approval of products that treat rare diseases. *See id.* § 360aa-360ee. *See also* Food and Drug Administration, *Orphan Drugs*, *at* <http://www.fda.gov/cder/handbook/orphan.htm>. The major provisions of the Orphan Drug Act are administered by the FDA Office of Orphan Products Development, *see generally* <http://www.fda.gov/orphan/index.htm>.

market drugs with those they have acquired from the manufacturers, and their customers are rarely even aware of the source of the product.

X. ENTER THE COUNTERFEITS

Given the complexity of the drug distribution network and its vulnerability to substitution of diverted products entering the supply chain, it is not surprising that enterprising individuals would exploit these weaknesses to further enhance their profits.

At the outset, it is important to define what is meant by the term “counterfeit” in the context of pharmaceutical drugs. Unsurprisingly, there is no international agreement on this. Part of the problem is the intersection of patent and trademark law, but equally important is the widely-held perception that life-saving medications do not fall neatly into a traditional intellectual property scheme.

The World Health Organization (“WHO”) defines counterfeits as follows:

Counterfeit medicines are part of the broader phenomenon of substandard pharmaceuticals. The difference is that they are deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit medicines may include products with the correct ingredients but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients.⁹²

This definition offers a tip of the hat to IP rights, but does not address commercial concerns relating to patents.

In the U.S., there is no explicit definition for counterfeit drugs *per se*, but rather a regulatory regime which incorporates patent, trademark, and regulatory considerations.

Pharmaceuticals may be patented in the U.S. for a period of 20 years.⁹³ As a practical matter, the patent term of most pharmaceuticals is less than that because, during the early part of the patent period, regulatory approval must be secured from the FDA. This can take anywhere from three to five years.⁹⁴ For a manufacturer, this means that the window of opportunity for significant profits on a new drug is relatively brief. Following expiry of the patent period, any approved party may

⁹² World Health Organization, *Fact Sheet No. 275*, available at <http://www.who.int/mediacentre/factsheets/fs275/en/> (February 2006).

⁹³ The 20-year patent term provision is contained in 35 U.S.C. § 154(a)(2) (2005).

⁹⁴ See FDA, CENTER FOR DRUG EVALUATION AND RESEARCH, 2004 REPORT TO THE NATION, IMPROVING PUBLIC HEALTH THROUGH HUMAN DRUGS 6-7, <http://www.fda.gov/cder/reports/rtn/2004/rtn2004.htm>. “There has been a slowdown – instead of the expected acceleration – in innovative medical therapies reaching patients. The medical product development path is becoming increasingly challenging, inefficient and costly.” *Id.* at 6. The report also notes new approvals and average duration of the approval process. *Id.* at 14-29. See also FOOD AND DRUG ADMIN., INNOVATION OR STAGNATION: CHALLENGE AND OPPORTUNITY ON THE CRITICAL PATH TO NEW MEDICAL PRODUCTS (2004), <http://www.fda.gov/oc/initiatives/criticalpath/whitepaper.html>.

According to federal statute, the FDA must “promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner.” 21 U.S.C. § 393(b)(1) (2005). *But cf.* Jennifer Kulynych, *Will FDA Relinquish the “Gold Standard” for New Drug Approval? Redefining “Substantial Evidence” in the FDA Modernization Act of 1997*, 54 FOOD & DRUG L.J. 127, 128 (1999) (“despite FDAMA’s emphasis on FDA’s duty to reach approval decisions promptly, the agency – traditionally headed by scientists, not politicians – takes a decidedly cautious approach to its role as gatekeeper of new medical products”), <http://www.fdpi.org/pubs/Journal%20Online/>.

make “generic” versions of the drug.⁹⁵ I use “generic” in quotations here, since this term engenders disagreement among nations. Outside the U.S., for example, “generic” versions of medications often become freely available once regulatory approval is granted, notwithstanding the adverse patent.

There *is* general international agreement on trademarks for pharmaceuticals. Even the holder of an expired patented medication may demand exclusive use of the registered name for his product. Even here, however, there exists conflicting interpretations of the law. In some countries, (e.g. India) the use of the word “generic” preceding the trademark is sufficient (e.g. generic Viagra) to avoid a problem. In the U.S., however, generic drug manufacturers use such circular references as “compare to” when referring to a registered mark.⁹⁶

The upshot of this disparity between U.S. and international standards is that “counterfeit” drugs in the United States may be perfectly fine elsewhere. For purposes of this article, the term will include *only* drugs which would be considered such by the most restrictive (i.e. WHO) definition. This necessarily excludes cases which are more in the nature of intellectual property disputes rather than *prima facie* health hazards.

Even under these restraints, counterfeits have become a serious challenge to the legitimate supply chain. Diversion almost always supplies the entry point for these products.

In the Carlow case noted above, the conspiracy included all of these elements. In February, 2005, two of his confederates, Domingo Gonzales and Julio Cruz pleaded guilty to massive counterfeiting and fraud involving the fake Lipitor.⁹⁷ Gonzalez and Cruz both admitted to participating in a two-pronged conspiracy that lasted from February 2002 to April 2003. First, the co-conspirators purchased genuine Lipitor intended for distribution in South America and illegally imported it into the United States. Second, the co-conspirators also bought and shipped equipment and chemicals to Costa Rica to manufacture counterfeit Lipitor, which they then illegally imported into the United States. They commingled the illegally imported Lipitor with the counterfeit Lipitor, and sold it in the United States.

Gonzalez and other members of the conspiracy caused genuine Lipitor tablets not intended for sale in the United States to be illegally imported by making fraudulent representations to the U.S. Customs Service. According to the federal information, members of the conspiracy purchased \$8.3 million worth of genuine Lipitor manufactured for distribution in a South American country, with the intent to illegally import the South American Lipitor into the United States.

Members of the conspiracy also purchased punches and dies from a company in the St. Louis, Mo. area, as well as various chemicals, to be used in manufacturing counterfeit drugs. Those materials were allegedly shipped to locations outside the United States—including Costa Rica and Honduras—for the purpose of setting up a drug manufacturing facility in a foreign country. Counterfeit Lipitor tablets were manufactured and smuggled into the United States.

⁹⁵ FDA, *Office of Generic Drugs*, <http://www.fda.gov/cder/ogd/#Introduction> (February 10, 2006).

⁹⁶ See, e.g., Department of Prevention, Assistance, Transition, and Health Access, *Vermont Health Access Pharmacy Benefit Management Program*, at http://www.dsw.state.vt.us/districts/ovha/pdl_06_01_04.doc (June 1, 2004). and Buygenericdrugs.com, *Pharmacy Prices*, http://www.buygenericdrugs.com/pharmacy/price_search_string.asp?alpha=WARFARIN (2006).

⁹⁷ See Lipitor, *supra* note 14.

Counterfeit drug labels were purchased from a company in the greater Miami, Fla. area, to be placed on bottles that contained the illegally imported and diverted tablets as well as bottles that contained the counterfeit tablets.

They then sold the counterfeit, illegally imported and diverted tablets to drug wholesalers in the United States. According to the federal information, Albers Medical Distributors, Inc., a Kansas City, Mo. firm, paid more than \$12.8 million to purchase the counterfeit, illegally imported and diverted tablets from members of the conspiracy.

According to the federal information, more than \$10.4 million in proceeds from the sale of the counterfeit, illegally imported and diverted Lipitor was deposited into a bank account held in the name of Pharma Medical at a bank in Tennessee between Nov. 18, 2002 and Feb. 4, 2003.

Count Two of the federal information charges Gonzalez with selling more than 4 million tablets of counterfeit Lipitor between December 2002 and March 2003.

Count Three of the federal information charges Gonzalez with selling numerous bottles containing counterfeit drugs. The labels on those bottles, according to the information, falsely stated that the drugs inside the bottles were manufactured by Pfizer. The labels did not bear the name and place of business of the true manufacturer, packer or distributor of the tablets.⁹⁸

This case is a paradigm of how counterfeits enter legitimate pharmacies. With minor variations, this template has been used by all of the scoundrels who infect the pharmaceutical distribution chain with bogus goods.

Once the diversion channel has been opened as described above, it is a simple matter for suppliers to “salt” their shipments with fakes. This, of course, magnifies their profits, since the acquisition costs for the counterfeits is almost always less than acquiring real, but diverted material.

In most cases, the substitution is never discovered. This is because of two unique features of drugs:

1. The evidence is almost always destroyed by ingestion or injection;
2. The effects (or lack thereof) of fake pharmaceuticals are generally attributed to the underlying disease itself. If the patient dies, for example, it will usually be determined that the cause of death was the disease (e.g. cancer) rather than the ineffective (counterfeit) drug intended to cure the disease.

Because of this, the actual incidence of counterfeit substitution for genuine product in legitimate pharmacies is unknown – and largely unknowable under the current distribution regime.

One of the most persistent problems has been the lack of pedigrees for pharmaceuticals. In 1999, the FDA proposed pedigree rules which would have enabled regulatory authorities and manufacturers to track the route their products took in the distribution chain.⁹⁹ These “paper pedigree” rules would have required

⁹⁸ See generally, Office of the U.S. Attorney, Western District of Missouri, *News Release*, Aug. 24, 2005, <http://www.usdoj.gov/usao/mow/news2005/milgrom.ple.pdf>.

⁹⁹ See 21 C.F.R. § 203.50 (2006). In 1999, §203.50 was added, effective Dec. 4, 2000. 64 Fed. Reg. 67721, 67761-67762 (1999), <http://www.gpoaccess.gov/fr/retrieve.html>. In 2000, the effective date for §203.50 was delayed until Oct. 1, 2001. 65 Fed. Reg. 25639 (May 3, 2000), <http://www.gpoaccess.gov/fr/retrieve.html>. In 2001, §203.50 was further delayed until Apr. 1, 2002. 66 Fed. Reg. 12851 (Mar. 1, 2001), <http://www.gpoaccess.gov/fr/retrieve.html>. In 2002, the effective date was further delayed until April 1, 2003. 67 Fed. Reg. 6646 (Feb. 13, 2002), <http://www.gpoaccess.gov/fr/retrieve.html>. In 2003, the effective date was further delayed until Apr. 1, 2004. at 68 Fed. Reg. 4912 (Jan. 31, 2003), <http://www.gpoaccess.gov/fr/retrieve.html>. Finally, in

paperwork to accompany drug shipments listing the buyer and seller of goods. These regulations were bitterly opposed by secondary wholesalers and even drug chains as burdensome. They also objected that manufacturers could use this information to eliminate competition by closing diversion channels.¹⁰⁰ Finally, there was (and remains) a significant question about the accuracy of paper pedigrees and the ease with which they could be falsified. As a result, the proposed rules were never implemented, and the supply chain is as vulnerable today as it was a decade ago.

A. THE SOLUTION?

The solution to the “open door policy” which permits counterfeit drugs onto legitimate pharmacy shelves is a combination of technology and law.

1. Technology

There are numerous technical steps which could be taken to both authenticate the legitimacy and to track the distribution of genuine pharmaceuticals (ATT or Authenticate, Trace/Track).

In the EU, most prescription drugs are dispensed in unit dose packaging (e.g. blister packs). This permits the manufacturer to include both overt and covert markings on the packages for identification. It also encourages consumers to verify that the goods are genuine by examining the package, rather than merely the color and shape of a tablet. In the U.S., most prescription drugs are currently dispensed in generic amber bottles which are filled at the pharmacy. This defeats most marking technologies, and does not permit consumers to act as a last line of defense against counterfeits. The U.S. should adopt the European system of prescription drug dispensing.

Radio Frequency Identification (RFID) is a fairly mature technology which is readily adaptable to pharmaceuticals. RFID is already used in hundreds of common applications ranging from highway toll cards to building keys. Its use has been mandated by both major retailers such as Wal-Mart and the Department of Defense for tracking inventories of all major products.¹⁰¹ Although RFID has some

2004, the effective date of §203.50 was further delayed until Dec. 1, 2006. 69 Fed. Reg. 8105 (Feb. 23, 2004), <http://www.gpoaccess.gov/fr/retrieve.html>.

¹⁰⁰ See, e.g., Letter from Bruce W. Hamilton, Ph.D., Professor of Economics, to Anthony L. Young, Esq. Re: Impact of New PDMA Rules on the Pharmaceutical Distributor Markets 5 (Oct. 26, 2000), reprinted in Anthony L. Young, Testimony on Behalf of the Pharmaceutical Distributors Association, Before the U.S. Department of Health and Human Services, FDA, Public Hearing on Regulations Implementing the Prescription Drug Marketing Act (October 26, 2000), available at http://www.fda.gov/ohrms/dockets/dailys/00/oct00/103000/103000.htm#_Toc498901371:

The requirement that every transaction be documented with a pedigree all the way back to the manufacturer means that the manufacturers and the Big 5 have vastly increased control over the paths followed by drugs from manufacturer to end user. The Big 5 have already demonstrated this control by refusing to provide pedigrees or authorized distributorships to small distributors. As noted in more detail below, there is a District Court finding that *local markets in this industry are ‘born to leak.’* This leakage, which will likely be greatly curtailed by the proposed rule change, is arbitrage in action.

(emphasis added).

See also FOOD & DRUG ADMIN., THE PRESCRIPTION DRUG MARKETING ACT: REPORT TO CONGRESS 14-15 (2001), <http://www.fda.gov/oc/pdma/report2001/>.

¹⁰¹ Regarding Wal-Mart, see, e.g., Demir Barlas, *Wal-Mart’s RFID Mandate*, at <http://www.line56.com/articles/default.asp?articleID=4710&TopicID=2> (June 4, 2003) and Computer Business Review Online, *Wal-Mart Quantifies RFID Benefits, Finally*, at

drawbacks such as cost,¹⁰² and is not easily adaptable to some goods such as soft paper products and some metal containers,¹⁰³ there are few technological barriers to its routine adoption in pharmaceutical packaging. More serious objections relate to privacy concerns¹⁰⁴ and access to the data generated by RFID systems.¹⁰⁵ These are valid questions, and must be addressed both by technological means (e.g. “killing” an RFID chip at the consumer point of sale)¹⁰⁶ and by strict regulation.

The pharmaceutical industry has been far behind other manufacturers in adopting tamper-resistant and ATT-friendly marking and coding in its packaging. There are dozens of innovative technologies available to do so, in addition to RFID. Other consumer products, such as denim jeans, for example, have literally numerous identifiers on them, while few life-saving drugs can be distinguished from fakes except in a sophisticated laboratory. Of course, many of these technologies would be defeated if distributors were permitted—and even encouraged—to manipulate packaging and products as they are under current law.

B. REGULATION

One proposal which should *not* be adopted is to significantly weaken the PDMA proscriptions on reimportation of Rx drugs. International diverters already flout this law through Internet sales. Breaching the remaining levee against diverted drugs would inevitably contaminate legitimate pharmacy stocks across the country.

Although there is some dispute between the Congress and the FDA concerning the latter’s authority to interdict mail-order drugs from abroad, this authority should be clarified.¹⁰⁷ Every day, thousands of packages arrive at the 13 international mail centers in the U.S. The parcels are floroscoped, and inspectors are able to discern the contents. It is literally impossible, however, for them to tell the *types* of drugs they see from mere images, so the packages are permitted to enter. A simple clarification that would permit FDA seizure of all such tablets is necessary *unless*

http://www.cbronline.com/article_news_print.asp?guid=2E769AED-4EF1-46EF-94C3-D8C078265B1A (Oct. 18, 2005). Regarding the U.S. Department of Defense, *see, e.g.*, Office of the Deputy Under Secretary of Defense (Logistics & Material Readiness), *Radio Frequency Identification (RFID)*, at <http://www.acq.osd.mil/log/rfid/index.htm> (February 23, 2006).

¹⁰² See e.g., High Jump Software, a 3M Company / Microsoft, *The True Cost of Radio Frequency Identification (RFID)* (2004), <http://www.highjumpsoftware.com/promos/rfid-cost-report.asp>.

¹⁰³ To address concerns on the effects of RFID on drug products that may be susceptible to change in their environment, the FDA developed a protocol for the Product Quality Research Institute (PQRI), a collaboration of FDA, academia, and industry. *See* Product Quality Research Institute, *PQRI News, PQRI to Gather Data on RFID Effects*, at <http://www.ipacrs.com/PQRI.html> (Feb. 2005). In addition, the Health Research Initiative of the Auto-ID Laboratories (based around the world at MIT, University of Cambridge, University of Adelaide, Keio University, Fudan University, and University of St. Gallen. *See Auto-ID Laboratory at MIT*, at <http://ken.mit.edu/web> (Apr. 22, 2005)) is conducting additional studies on the effects of radio-frequency on various drug products. *See* FOOD & DRUG ADMIN., COMBATING COUNTERFEIT DRUGS: A REPORT OF THE FOOD AND DRUG ADMINISTRATION ANNUAL UPDATE (2005), <http://www.fda.gov/oc/initiatives/counterfeit/update2005.html>.

¹⁰⁴ *See, e.g.*, Derren Bibby, *Squaring the Circle with RFID and Privacy*, at <http://www.crbuyer.com/story/38385.html>.

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ *See* CONGRESSIONAL RESEARCH SERVICE, CRS REPORT FOR CONGRESS RL32191: PRESCRIPTION DRUG IMPORTATION AND INTERNET SALES: A LEGAL OVERVIEW (Oct. 4, 2004), <http://www.opencrs.com/document/RL32191/2004-10-04%2000:00:00>. *Cf.* HHS TASK FORCE ON DRUG IMPORTATION, U.S. DEP’T OF HEALTH & HUMAN SERVS., REPORT ON PRESCRIPTION DRUG IMPORTATION (2004), <http://www.hhs.gov/importtaskforce/>.

the package was accompanied by an authorization form listing the contents with specificity, the buyer, the sender, and a certification that the recipient had a valid prescription for the contents. All others would be marked “return to sender.”

In addition, the FDA should be granted authority to regulate the drug distribution network in the country. The current system of overlapping controls and licensure of wholesalers creates ample opportunities for counterfeiters to game the system.

The FDA’s resources should also be increased to permit adequate enforcement of drug distribution—especially the Office of Criminal Investigation. As it is, there are fewer than 300 FDA/OCI agents in the United States. This should be increased ten-fold.

Regulations (or laws, if necessary) should be promulgated to prohibit tampering with packaging of drugs and make regulatory changes necessary to encourage packaging in unit doses.

Finally, deployment of RFID technology on pharmaceuticals should be expedited and regulatory changes to strictly limit access to data and protect consumer privacy must be implemented. The deployment of RFID should be specifically geared to ascertaining pedigrees from the manufacturer’s loading dock to at least the dispensing pharmacy level. Secondary wholesalers are already on record as opposing this system insofar as it might enable manufacturers to identify, and subsequently eliminate these “leaks” in their distribution chain. While this raises some legitimate questions, the very purpose of pharmaceutical regulation in the U.S. is to assure the public of the medication’s safety. Since *all* of the counterfeit drugs which have entered the legitimate market have been handled by these secondary marketers, protecting their “right” to divert product must take second place to public health. Since manufacturers are usually held responsible for assuring the safety of their drugs, they must be given the right (and *duty*) to assure that their products *remain* safe when taken by the ultimate consumer. This additional burden for manufacturers must be accompanied by a realistic means for them to conform to the requirements. Fixing “leaks” in their distribution chain is one method of doing so.