Counterfeit-Resistant Technology: An Essential Investment to Protect Consumers and to Avoid Liability

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Spam emails advertising low-priced drugs persistently litter email in-boxes. In addition to being a nuisance and a constant reminder that American consumers pay exorbitant prices for prescription drugs, the spam emails do not disclose the risks of buying discounted drugs. While the discounted Viagra, Cialis, and many other drugs are a bargain hunter's dream come true, drugs sold on the internet, purchased across U.S. borders or other non-traditional channels, and even some purchased through traditional channels, place consumers at risk as they lack guarantees of authenticity, efficacy, and safety.

This note will outline the increasing prevalence of counterfeit drugs in the United States; the increasing threat counterfeit drugs pose to U.S. consumers; the emerging technologies developed and employed by pharmaceutical companies to combat counterfeit drugs; the inadequacy of the current laws to address the issue; and the potential liability facing manufacturers who fail to employ such technologies. The first section will provide a background and history of counterfeit resistant technologies. The second section will address current legislation and regulations relating to these technologies. The third section will present the precedent for imposing tort liability for

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1 See 21 U.S.C. § 321(g)(2) (2004) (defining counterfeit drug). "The term 'counterfeit drug' means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor." Id.
failing to employ available safety technologies. The last section will analyze current tort law in relation to the current climate in the biomedical industry. While this issue is novel to the biomedical industry, well-documented cases of negligence liability for failure to employ available safety technology exist in other industries, and the pharmaceutical and biotechnology markets are beginning to face claims on similar grounds.\(^2\)

I. Development of Counterfeit Resistant Technology in the Biomedical Industry.

Today, the average timespan from when an experimental drug enters the initial discovery phase to when it may gain Food and Drug Administration ("FDA") approval exceeds 15 years.\(^3\) Of all the new drug studies undertaken, the current estimate is that one in five thousand actually makes it to market.\(^4\) This lengthy process amounts to an average cost in research and development exceeding $500 million per product.\(^5\) With costs continuing to escalate, drug manufacturers push to maximize profits before the end of their exclusive right to market a pharmaceutical or biomedical product.\(^6\) In


\(^3\) Pharmaceutical Research and Manufacturers of America, Pharmaceutical Industry Profile 2005, (Washington, D.C.: PhRMA, March 2005), Feb. 28, 2006, available at http://www.phrma.org/2005_industry_profile/ (last visited November 29, 2006). (www.phrma.org/2005_industry_profile/ (reporting average time from basic research phase to FDA approval and large-scale manufacturing is 15.5 years). The Pharmaceutical Research and Manufacturers of America (PhRMA) is a non-profit industry trade group representing research-based pharmaceutical and biotech companies. Id. PhRMA routinely surveys the pharmaceutical and biotech industries, publishes industry reports, promotes philanthropy, and works to preserve and enhance the industry's interests. Id.

\(^4\) See Drug Approvals – From Invention to Market . . . A 12-Year Trip, MEDICINE.NET.COM, July 14, 1999, available at http://www.medicinenet.com/script/main/art.asp?articlekey=9877. (last visited November 29, 2006). (outlining general clinical trials process and timeline). Research indicates that five of every five thousand drugs that enter preclinical testing of clinical trials progress to human testing. Id. Of those five experimental drugs tested on people, statistics indicate that only one will gain U.S. Food & Drug Administration approval. Id.

\(^5\) See PhRMA, supra note 3 (predicting average discovery cost per drug would range from $500 million - $600 million in 2004).

\(^6\) 35 U.S.C. § 154(c) (2002) (defining patent and setting patent term at 20 years from date of application).
addition to the pressure to recoup their investment before the market opens to generic 
drugs, pharmaceutical companies also find themselves competing against the lucrative 
and expanding business of counterfeit drugs.7

The pharmaceutical industry is a $172 billion industry in the United States and 
exceeds $300 billion worldwide.8 This expanding marketplace for pharmaceutical 
products presents enormous opportunity not only for legitimate drug makers but also 
for counterfeiters who introduce “look-alike” drugs.9 The World Health Organization 
(“WHO”) estimates that such “look-alike” or counterfeit drugs comprise as much as ten 
percent of pharmaceuticals worldwide, and in some countries constitute up to fifty 
percent of the drug supply.10 Although the U.S. Food and Drug Administration strictly 
regulates the development and sale of prescription drugs in the United States, increased 
patient access to drugs through less conventional sources such as the internet and 
foreign pharmacies allows counterfeit drugs to more freely enter U.S. markets.11 In a 
country that maintains the highest standards for prescription drugs, even a moderate rise

7 See Sarah Lueck & Laurie McGinley, Move to Import Medicines: Boon or Boondoggle?, WALL ST. J., 
Oct. 13, 2000, at B1 (mentioning drug companies’ concern about counterfeit drugs entering 
United States); see also PhRMA, supra note 3 (reporting generic drugs occupied a 47% share of 
pharmaceutical market by 2000). In 1986, generic drugs comprised 18.6% of the drug market. 
Id. The rapidly expanding generic market highlights the same economic factors that encourage 
drug counterfeiting; once the FDA approves a specific combination of ingredients in a drug, and 
after the patent expires, the cost to replicate a known and proven drug is minimal. Id.

8 See Charles Haddad, Fake Drugs, Real Disaster, BUS. WK., Feb. 9, 2004, at 44 (demonstrating 
counterfeit drug producers’ financial incentives to expand foreign counterfeit operations into 
United States).

9 See FDA Week, infra note 10.

10 See John Taylor, Associate Commissioner for Regulatory Affairs of the U.S. Food and Drug 
Administration, Introduction to the U.S. Food and Drug Administration’s Public Meeting on 
Anti-Counterfeit Drug Initiative (October 2003), available at http://www.fda.gov/oc/- 
itinitiatives/counterfeit/oct2003meeting/intro.html. (last visited November 29, 2006). (noting 
counterfeit drugs less prominent in United States than in other countries); see also Raphael 
Minder, Interpol Urges Countries’ Help in Fight Against Counterfeitors, FIN. TIMES, May 26, 2004, at 13 
(reporting widespread disregard and ignorance among world governments regarding counterfeit 
operations); see also Marc Kaufman, FDA Looks to Chips to Thwart Drug Counterfeiters; Voluntary Plan 
Envisions Manufacturers Adopting Electronic Track-and-Trace Technology by 2007, WASH. POST, Feb. 19, 
2004, at A10 (summarizing growing challenges counterfeit drugs present to FDA); see also Bill to 
Fight Counterfeits Would Require RFID Tags for All Drugs, FDA WEEK, Mar. 3, 2006 (reporting 
World Health Organization estimates that 10% of the world pharmaceutical market is currently 
fake and that 20% will be counterfeit by 2010).

11 See Ceci Connolly, A Small Win for Proponents of Drug Importation; Vote of Pfizer Shareholders Will 
Put Issue on Next Annual Meeting Agenda, WASH. POST, April 23, 2004, at E01 (highlighting safety 
concerns of legalizing drug importation from Canada); Kaufman, supra note 10 (FDA counterfeit 
drug investigations in United States four times higher than pre-2000 rate).
in counterfeiting schemes alarms the healthcare community, the drug industry, and regulatory agencies.12

In addition to subjecting consumers to health risks, the financial concerns that counterfeit drugs present to pharmaceutical companies have caused some manufacturers to reevaluate their business priorities.13 The estimated rate of return on an investment for drug counterfeiters is as high as 2000%.14 This potential profit margin far outweighs the risks for counterfeiters and slices into potential profit to the pharmaceutical industry, leaving the industry with little option but to explore technological methods to combat counterfeiting.15

The precursor to counterfeit resistant technologies arose out of the contaminated Tylenol incident in 1982.16 After several people died from taking Tylenol capsules containing cyanide, manufacturers responded by shrink-wrapping the bottles.17 Since 1982, the need to prevent the tampering with over-the-counter medications has given way to a far more continuous and systematic threat to the drug supply.18 Sophisticated counterfeiting systems now exist that introduce fake drugs to consumers

13 See Prescription Drugs, infra note 64.
14 See Merri C. Moken, Note, Fake Pharmaceuticals: How They and Relevant Legislation or Lack Thereof Contribute to Consistently High and Increasing Drug Prices, 29 Am. J.L. & MED. 525, 531 n. 69 (2003) (discussing low cost of ingredients and high returns in counterfeit drug sales). Sources estimate that the counterfeit pharmaceutical trafficking may yield as much as $32 billion worldwide and $12 billion in the United States each year. Id. at 531-32 n. 73. By 2010, counterfeit drug trafficking is expected to be a $75 billion business worldwide. Peter J. Pitts, Pharmaceutical Fakey Is Healthcare Terrorism, BALTIMORE SUN, Aug. 15, 2006, at 11A.
15 Moken, supra note 14, at 525-26 (comparing cost of producing counterfeit pharmaceuticals in relation to brand name drugs).
16 See Laura Butalla, Fighting for Secure Packaging: Counterfeiting is Still on the Rise; Security Technology is Racing to Stay One Step Ahead of the Fakes, CONVERTING MAGAZINE, Nov. 1, 2003, at 28 (noting death of seven people who swallowed cyanide laced Tylenol prompted companies to change packaging).
17 Id. (stating shrink wrap was beginning of action to protect against counterfeiting and tampering).
18 Id. (outlining experimental technologies currently in development to protect against sophisticated fakes). In an effort to safeguard their products, companies have developed and continue to develop “multi-layer protection systems” such as holograms, hidden images, microtext, complex numbering systems, different inks, and Radio Frequency Identification. Butalla, supra note 16, at 28.
through traditional distribution channels as well as by exploiting more novel outlets like the Internet. These fake drugs are visibly indistinguishable from the real drugs both in terms of the packaging design and the appearance of the product itself. Such highly deceptive and dangerous “look-alikes” have prompted pharmaceutical manufacturers to respond.

As drug manufacturers reap the benefits of high priced drugs in the U.S. market, they have simultaneously lost potential sales to illegitimate entities providing lower priced imposters to innocent patients. In recent years, Pfizer’s blockbusters Viagra and Lipitor, as well as Johnson & Johnson’s Procrit, have fallen prey to major counterfeiting schemes. Counterfeiters’ success in replicating tablets, and the lack of

19 See Haddad, supra note 8 (discussing Florida counterfeiters who move drugs through legitimate wholesalers). The realization that wholesale distributors trade fake drugs back and forth until the drugs are no longer traceable led several companies, including Eli Lilly, Pfizer, and Johnson & Johnson, to eliminate many of their intermediate distributors in favor of either using select company-approved distributors or dealing directly with customers. Id. See also Ashworth v. Albers Medical, No. 2:05-0139, 2005 U.S. Dist. LEXIS 22596, at *5-9 (S.D. W. Va. July 25, 2005) (outlining how counterfeit drugs infiltrated legitimate distribution channels and made their way to consumers via major retail pharmacy).

20 See Tom Masland, Vern E. Smith, & John Taliaferro, Confessions of a Counterfeiter, NEWSWEEK, Nov. 5, 1990, at 38 (reporting drug counterfeiter’s ability to make near-perfect fakes). See generally United States v. Naghdi, No. 90-50300, 1992 U.S. App. LEXIS 1401 (9th Cir. 1992). After the U.S. Customs Service arrested Javid Naghdi for the second time on drug counterfeiting charges, the Government disclosed Naghdi’s resources during the trial at which he was convicted. Masland, supra. The case exposed counterfeiters’ access to pill pressing equipment, printing presses and bar code technology that enabled the fakes to pass as real even when scanned by pharmacists’ electronic scanners designed to authenticate packaging. Id. An alert pharmacist detected the only flaw in the fake drugs: the pills’ strange odor. Id. See also 21 U.S.C. § 321 supra note 1 (defining counterfeit drug as unauthorized reproduction of drug, package or label).

21 See Butalla, supra note 16 (discussing increased efforts to curb counterfeiting).

22 See Peter S. Goodman, China’s Killer Headache: Fake Pharmaceuticals, WASH. POST, Aug. 30, 2002, at A01, (noting major difference between counterfeiting drugs versus other products). There are countless different counterfeit products available to those who wish to buy them, but the major difference between buying a fake Rolex watch and buying fake pharmaceuticals is the awareness that what one buys is a fake. Id. While most purchasers realize when a watch is not real, or at least may be counterfeit, drugs counterfeiters make their money by being the last in the chain to know the drug is fake and by selling the drug at premium prices to unsuspecting buyers. Id.

success in stopping these counterfeiting operations, motivated companies to explore new methods of packaging and alternative product designs in order to render products less prone to imitation.\textsuperscript{24}

Pharmaceutical companies have increased efforts to develop technologies that make their drugs less susceptible to counterfeiting. Many drug makers display holograms on the packaging to signify their authenticity.\textsuperscript{25} Other manufacturers produce their tablets in unusual shapes that traditional counterfeiting machines cannot imitate.\textsuperscript{26} The pharmaceutical industry, however, is not ignorant of the fact that even such revolutionary changes in the appearance of a tablet or its packaging will only serve as temporary impediments to counterfeiters.\textsuperscript{27} Far more sophisticated advances in counterfeit-resistant technology, such as electrostatic design, present more promising roadblocks to counterfeit operations.\textsuperscript{28} Because these designs are part of the coating itself, and not a stamp applied to an already coated tablet, the designs are nearly impossible to replicate without utilizing the secret technology.\textsuperscript{29} Other sophisticated technologies have also enhanced the security features of packaging and protect product is easier.\textsuperscript{24} See also Patricia Reaney, \textit{Half of Internet Viagra Could Be Fake}, Reuters (Sept. 29, 2004) (reporting that recent study conducted by British scientists indicated that as much as fifty percent of Viagra sold over the Internet may be fake), available at http://www.abc.net.au/-science/news/stories/s1209496.htm. (last visited November 29, 2006).

\textsuperscript{25} See Report from Giuliani Partners, L.L.C. to Pharmaceutical Research and Manufacturers of America, \textit{Examination and Assessment of Prescription Drug Importation From Foreign Sources to the United States}, May 11, 2004, available at http://www.fda.gov/ohrms/dockets/dockets/04n0115/04N-0115_emc-000013-02.pdf. (last visited November 29, 2006). (reporting various technologies currently available to fight counterfeiting). Among the counterfeit resistant technologies in existence and available for implementation are electronic track and trace technologies such as Radio Frequency Identification ("RFID") and bar coding; holograms, watermarks, color-shifting inks, fluorescent inks, and chemical agents; "unit of use packaging"; and authentication tests, which the original manufacturers must perform. \textit{Id.} at 5.

\textsuperscript{26} \textit{Id.} (listing counterfeit resistant technologies currently employed by industry).

\textsuperscript{27} See Haddad, supra note 8 (reporting counterfeiters now create near perfect labels, bar codes, company logos, and holograms).

\textsuperscript{28} Phoqus - UniQ\textsuperscript{TM} brand enhancement and protection, available at http://www.phoqus.com/-sysuniq.html. (last visited September 18, 2006). Phoqus Pharmaceuticals developed UniQ\textsuperscript{TM} brand protection, which uses static electricity to incorporate swirls, overlapping designs, and layered coloring during the actual coating process of the tablet. \textit{Id.} Coating refers to the process by which a tablet is sealed and colored, often with a paint that gives it a specific color or appearance, after which a drug company traditionally stamps the drug name or logo on to the tablet. \textit{Id.} Phoqus Pharmaceuticals' electrostatic design process is a trade secret that provides enhanced protection to those pills and tablets to which it is applied. \textit{Id.}

\textsuperscript{29} \textit{See} Phoqus, supra note 28.
integrity to the extent that counterfeiting is so difficult that counterfeiters have no financial incentive to attempt forging those products. Another security feature, Radio Frequency Identification ("RFID"), is one of the most promising and realistic safeguards because the technology can be utilized to trace drug shipments from the point of manufacture to when the consumer receives it. The capital resources that drug makers are dedicating to these technologies indicates multiple incentives to counterfeit-proof their products.

Counterfeit drug sales not only deprive the true manufacturer out of revenue to which it is rightfully entitled but also have the potential to damage a product's image. Law enforcement officials continue to discover counterfeit drugs that contain all, some, or none of the active ingredients in the approved drug, and in some cases, the counterfeits contain harmful substances. As news reports of counterfeiting of

30 See generally Hueck Folien company website, available at: http://www.hueck-folien.de/English/willkommen.htm. (last visited September 21, 2006). For example, manufacturers often package prescription and over the counter medications in blister packets that range in size and design. Id. Traditionally, a blister packet contains multiple tablets which are visible through a translucent “bubble-like” plastic package, and consumers can pop or push the tablets out of the underside of the packet, often made of a thin layer of cellophane-like plastic covered by foil. Id. Hueck Folien’s technology greatly enhances the security features of blister packets in order to protect the integrity of its drugs. Id. Protecco® uses a combination of up to 250 security technologies in its packaging, including holograms, matrix printing, UV-fluorescent characteristics, multi-colored schemes, and micro-texts that make counterfeiting so difficult that counterfeiters have no financial incentive to even try to forge Hueck Folien’s products. Hueck Folien company website, supra.

31 See FDA, infra note 45 (discussing FDA recommendations for companies to employ RFID technology to track and trace drug shipments). RFID technology will be utilized by embedding computer chips into packaging and labeling that can be traced along each stage of the distribution chain. Id. Sensors at warehouses and pharmacies use radio waves to activate the chips, which are electronically scanned and stamped, thus producing a shipping history and electronic pedigree. Id. Such labels should enhance safety because they will contain information as to where the drug was developed and where it moved along the distribution channels, as well as potential tracing technology whereby a drug’s location can be traced through radio frequency technology. See Kaufman, supra note 10.


33 See Tom Masland, Vern E. Smith, & John Taliaferro, Confessions of a Counterfeiter, NEWSWEEK, Nov. 5, 1990, at 38 (describing ingredients of several fake drugs). In one case, counterfeit burn medications in Mexico contained dirt, sawdust or coffee and increased infection rather than healing burns. Id. In Africa, some tablets contain nothing but talcum powder. Id. See also
particular drugs reach consumers and healthcare providers who prescribe the drugs, patients will inevitably become skeptical of certain brands or categories of drugs most prone to counterfeiting.\textsuperscript{34} Drug manufacturers are responding to this threat to their products' images in varying degrees.\textsuperscript{35}

In addition to developing their own counterfeit-resistant technologies, drug companies have formed alliances such as the Quality Brands Protection Committee to dismantle counterfeit operations throughout the world.\textsuperscript{36} This increased technological development and collaborative effort to address counterfeiting represents the industry's commitment to wage war on the counterfeiters and to safeguard the integrity of its products.\textsuperscript{37}

\section*{II. Legislation Addressing Counterfeit Drugs}

Current laws, both in the United States and even more so at the international level, inadequately combat counterfeit drug makers.\textsuperscript{38} In countries such as China and


\textsuperscript{34} See Sarah Lueck, Drug Industry Lobbies to Block Low-Priced Imports, WALL ST. J., July 11, 2001 at B2 (reporting industry fears publicity about counterfeit drug dangers will alarm consumers).\textsuperscript{35} See John Dempsy, Executive Director of Trade Relations and Brand Security for Ortho Biotech Products, LP, a Johnson & Johnson company, Industry: Development & Distribution, Speech to Stakeholder Meeting of U.S. Department of Health and Human Services Importation Task Force (Apr. 5, 2004), transcript available at http://www.hhs.gov/importtaskforce/- session2/transcript.html. (last visited November 29, 2006). Dempsy reported that by the end of 2004, Johnson & Johnson intended to equip the packaging of those products that account for 80\% of the company's sales with at least one "anti-counterfeiting feature." \textit{Id.}

\textsuperscript{36} See Goodman, \textit{supra} note 22 (explaining international effort to fight counterfeiting in high risk countries). The Quality Brands Protection Committee is a group of eighty-three companies led by an attorney for Johnson & Johnson in China. \textit{Id.}

\textsuperscript{37} See Goodman, \textit{supra} note 22 (demonstrating pharmaceutical industry's growing willingness to lead covert missions to confront counterfeit operations).

\textsuperscript{38} See Goodman, \textit{supra} note 22 (highlighting the ineffectiveness of laws in Asian nations where local authorities turn a blind eye to counterfeiting). Examples of willful blindness include: cases when counterfeiters evidently have been "tipped off" before authorities conduct raids; instances when authorities discover counterfeit operations but are only willing to conduct raids if compensated by the drug company whose drug is the subject of the counterfeiting; and the reality that administrative agencies lack power to take effective action have jurisdiction over investigations of counterfeiting operations. \textit{Id.}
India, which are believed to be the centers of operation for many of the worldwide counterfeiting enterprises, punishments for counterfeiting can range from nominal fines to short prison sentences.\(^3\) Additionally, the laws and policies of some countries have facilitated counterfeiting in the past and in the present.\(^4\) Domestically, legislation concerning counterfeit pharmaceuticals has been and continues to be insufficient.\(^4\)

Traditionally, the Federal Food, Drug and Cosmetic Act ("FDCA") has served as the loose governing authority over the issue of counterfeit pharmaceuticals.\(^4\) The FDCA requires that all imported drug shipments meet certain standards in order to gain entry into the U.S.\(^4\) Additionally, in 2003, the FDA mandated that all pharmaceutical products contain a bar code as a means to identify the origin and distribution path of each product.\(^4\) In practice, however, this measure is insufficient to combat sophisticated counterfeiters who not only have access to bar code technology, but have also found ways to circumvent these regulations and introduce their fake drugs into

\(^{39}\) See Goodman, supra note 22 (citing examples of nominal penalties for drug counterfeiting). China is increasing efforts to eliminate drug counterfeiting; however, the maximum criminal sentence for counterfeiting drugs is seven years except when an injury can be directly attributed to the specific counterfeit, in which case the death penalty is available. Id. In reality, when the Chinese government catches counterfeiters, the most common penalties are civil fines. Id. On the occasion when the government pursues criminal charges the prison sentence is generally short, and cases carrying the death penalty are rare. Id.

\(^{40}\) See Tom Masland & Ruth Marshall, A Real Nasty Business, NEWSWEEK, Nov. 5, 1990, at 36 (pointing to Italy as a major center of counterfeit drug operations). Prior to 1978, Italy did not recognize international drug patents and it is widely suspected that the lack of controls over pharmaceuticals fostered a breeding ground for counterfeit operations. Id. See also Peter J. Pitts, Pharmaceutical Fakery Is Healthcare Terrorism, BALTIMORE SUN, Aug. 15, 2006, at 11A. (reporting North Korea now manufacturing and selling counterfeit drugs).

\(^{41}\) See infra notes 46, 48 and 58 (citing multiple attempts by Congress to enact more stringent anti-counterfeiting legislation aimed to amend and supplement current Federal laws).


\(^{44}\) Letter from Jay Fraser, President & CEO, Tracer Detection Technology Corporation, to John Taylor, Associate Commissioner for Regulatory Affairs, U.S. Food & Drug Administration (Aug. 11, 2003) (petitioning FDA to consider recommending Tracer’s counterfeit-resistant technologies to pharmaceutical and biotech industries), available at http://www.fda.gov/ohrms/dockets/dailys/03/Nov03/110503/03N-0361-emc-000014-05.doc. (last visited November 29, 2006). In 2003, the FDA conducted a 60-day review of current available counterfeit-resistant technologies. Id. Tracer Detection Technology Corporation urged the FDA to consider its newly developed and licensed counterfeit resistant technology that employs a random pattern of fibers. Id. The company embeds the pattern into product labels and tamper evident seals. Id. The random configuration of fibers makes the chance of counterfeiting a code less than one in 1000 trillion. Fraser, supra.
legitimate distribution channels.45

In 2003, the 108th Congress attempted to initiate a broader plan when the House of Representatives passed H.R. 2427, the Pharmaceutical Market Access Act of 2003 ("PMAA").46 The proposed legislation, however, died in the Senate.47 The same sponsor, Representative Gil Gutknecht of Minnesota, along with other law makers, revived the efforts to pass more demanding legislation regulating the pharmaceutical markets when he re-introduced the bill as H.R. 328 in the 109th Congress.48 Senator David Vitter of Louisiana introduced companion legislation in the Senate.49 These Congressmen revived the PMAA of 2003 in H.R. 328 and S. 109 largely to address the relatively high cost of U.S. prescription drugs compared to those in Canada that are available for a fraction of the price charged in the U.S.50 While the sponsors may have aimed to lower drug prices, they also recognized the safety concerns posed by drugs that filter into the U.S. from unknown origin.51 This measure, which contravenes the PMAA's cost saving purpose, demonstrates clear recognition that drug counterfeiting is growing in the United States and that current controls are inadequate to manage the problem.52

52 PMAA, supra note 46.
The PMAA of 2005 would amend and supplement the current provisions of the FDCA.\textsuperscript{53} H.R. 328 and S. 109 set forth counterfeit-resistant packaging requirements for all drugs imported into the United States.\textsuperscript{54} The PMAA of 2005 contains a provision requiring all pharmaceutical manufacturers to implement counterfeit-resistant technology functionally equivalent to that used by the U.S. Treasury; or in the alternative, it requires that the packaging of all drugs imported contain “overt optically variable counterfeit-resistant technologies” as well as “additional layers of non-visible covert security features.”\textsuperscript{55} Additionally, manufacturers would be required to incorporate counterfeit-resistant technologies into “multiple elements of the physical packaging... including blister packs, shrink wrap, package labels, package seals, bottles, and boxes.”\textsuperscript{56}

To date, the latest versions of the PMAA have not been approved by committee in either House.\textsuperscript{57} As a result, Congressmen Gutknecht and Senator Vitter recently introduced new bills, which sever the drug re-importation issue from drug safety.\textsuperscript{58} H.R. 4829 and S. 2668, both titled the Reducing Fraudulent and Imitation Drugs Act (“RFIDA”), would require the implementation of specific counterfeit resistant technologies.\textsuperscript{59} These latest bills demonstrate the continued importance and need for

\textsuperscript{54} Id.  
\textsuperscript{55} Pharmaceutical Market Access Act of 2005, H.R. 328, 109th Cong. § 6b (2005). The bill further defines overt optically variable counterfeit-resistant technologies as technologies that are “visible to the naked eye, providing for visual identification of product authenticity without the need for readers, microscopes, lighting devices or scanners.” Id.  
\textsuperscript{56} See also Review & Outlook: The Color of Money: Is That Andrew Jackson on the Twenty – or Lord Byron?, WALL ST. J., May 16, 2003, at W17 (reporting on the new design of paper bills). The Bureau of Printing and Engraving employs the latest technology to deter counterfeiting by inserting thin security strips into paper money, implanting water marks on bills, adding metallic eagles, and by using color-shifting ink that changes colors under different lighting. Id.  
\textsuperscript{57} See Library of Congress web site, at http://thomas.loc.gov/.  
\textsuperscript{59} Reducing Fraudulent and Imitation Drugs Act of 2006, H.R. 4829, 109th Cong. § 2(a) (2006); Reducing Fraudulent and Imitation Drugs Act of 2006, S. 2668, 109th Cong. § 2(a) (2006). The RFIDA would require that the packaging of prescription drugs be safeguarded by Radio Frequency Identification Technology; “tamper-indicating technologies; and blister security packaging when possible.” H.R. 4829 § 2(a); S. 2668 § 2(a). Additionally, the Acts recommend implementation of “overt optically variable counterfeit-resistant technologies,” such as those currently used in U.S. currency, which enable consumers to authenticate a prescription drug without the aid of “readers, microscopes, lighting devices, or scanners.” H.R. 4829 § 2(c); S. 2668 § 2(c).
counterfeit resistant technologies in the biomedical markets.

In addition to the PMAA and RFIDA legislation, the FDA now recommends that all pharmaceutical manufacturers incorporate RFID technology into packaging by 2007. RFID can present a major safeguard because it will provide a distribution history and create an electronic pedigree of the shipment that counterfeit drugs will not have. Although the pharmaceutical and biotechnology industries have been resistant to increased FDA regulation in this field, in reality, the safety precautions recommended by the FDA fall far short of the research and development of counterfeit resistant technologies initiated voluntarily by many drug manufacturers.

Despite general resistance to FDA intervention, at least some members of the pharmaceutical and biotechnology industries appear to concur with the FDA's position on RFID technology. Recently, several major pharmaceutical companies pledged to implement RFID technology. The common thread between the drugs targeted for RFID is their susceptibility to counterfeiting, tampering, diversion and theft. Consequently, use of the technology will remain limited to blockbuster drugs and leave the majority of drugs under-protected. This under-utilization of available counterfeit resistant technologies in the pharmaceutical and biotechnology industries may expose manufacturers to liability.

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60 See Bill to Fight Counterfeits Would Require RFID Tags for All Drugs, FDA WEEK, Mar. 3, 2006; see also FDA, supra note 45 (FDA endorses use of RFID technology as viable counterfeit-resistant technology).
61 See FDA, supra note 45.
62 See Phoqus Pharmaceuticals, supra note 28; see also Hueck Folien, supra note 30 (providing examples of art technology developed by private industry to combat counterfeiting).
63 See Prescription Drugs, infra note 64. Agreement with the FDA as to the utility of RFID technology may be inferred by the willingness of major pharmaceutical manufacturers to implement RFID even though such implementation is only recommended, not required. Id.
64 See Prescription Drugs; Radio Tags to Vouch for Drugs' Legitimacy, LAW & HEALTH WKLY., Dec. 11, 2004, at 293 (reporting Pfizer announced that by end of 2005 shipments of Viagra will be tracked using RFID; Purdue Pharmaceuticals will implement RFID and color-shifting ink with OxyContin; and GlaxoSmithKline intends to equip some of its products with RFID track and trace technology). Such industry cooperation combined with the FDA's own initiatives leads to anticipated widespread use of RFID by 2007. Id.
65 Id.
66 Id.
67 See discussion infra Parts III and IV.
III. History and Development of Case Law

History indicates that a company can become exposed to tort liability for its failure to employ safety technology that is available and renders its product(s) safer for consumers. At this time, existing counterfeit resistant technologies have the capacity to make many drugs safer. In fact, many companies have begun to use some forms of counterfeit resistant technology. With these technologies available and continuously enhanced for future use, companies that choose not to employ protections may be liable to consumers who suffer injuries after taking counterfeit drugs which they believed to be the real thing. The following section will present possible legal theories under which drug manufacturers may be held liable for their failure to employ counterfeit resistant technologies.

A. Strict Tort Liability

The test to determine strict products liability based on an unreasonably dangerous design follows a traditional risk-utility analysis. Factors to be considered include: 1) the usefulness and desirability of the product; 2) the safety features of the product; 3) the availability of an alternative and safer product design; 4) the manufacturer's ability to correct the safety deficiency without diminishing the product's efficacy or rendering the product too expensive; 5) the consumer's ability to avoid the danger by careful use of the product; 6) the consumer's knowledge of the potential danger posed by the product based on general public knowledge or the manufacturer's sufficient warnings or instructions; and 7) the feasibility of the manufacturer apportioning the cost of improvements through pricing mechanisms or liability insurance. In addition to the seven factors outlined in the treatise, the plaintiff bears the burden of demonstrating foreseeability of the product's danger.

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68 See discussion infra Part III.
69 See supra notes 24, 28, and 30.
70 See supra notes 24, 28, 30, and 64.
72 Id. (listing factors).
73 RESTATEMENT (THIRD) OF TORTS § 2, cmt. p (2004) (stating "foreseeable product misuse, alteration, and modification must be considered in deciding whether an alternative design should have been adopted"). The Restatement also notes that the post-sale conduct of the consumer may be so unreasonable that the manufacturer has no duty to modify a product's design to protect against such use. Id. On the other hand, even where a product is misused in a manner unintended by the manufacturer, that product may still be defective if the risks associated with the unintended use of the product are reasonably foreseeable and outweigh the benefits of the design. See also White v. Smith & Wesson Corp., 97 F. Supp. 2d. 816, 827 (N.D. Ohio 2000).
Generally, a manufacturer of a product is not liable under strict products liability for design defects if, after the product leaves the manufacturer's control, a third party substantially modifies the product and such modification causes injury to the consumer. Exceptions to this rule, however, may be made when it is objectively foreseeable that a substantial change in a product will cause injury, the modification in fact caused injury, and the plaintiff presents evidence that an alternative design would have prevented the modification that caused the injury. Therefore, a design defect that is reasonably foreseeable to lead to substantial injury, even if that injury is caused by alteration to the product only after it leaves the manufacturers' exclusive control, can still result in strict products liability.

Legal standards occasionally originate when an industry recognizes a need to correct potential deficiencies in their products, even when government has not imposed substantial regulation in the area. The potential for liability increases greatly by frequent use of a safer technology in the marketplace. In general, an industry-imposed standard is a basis for legal liability only when a large percentage of the industry uses a

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74 63A AM. JUR. 2D Products Liability § 1004 (2005).
75 63A AM. JUR. 2D Products Liability § 1004 (2005). See also Brown v. United States Stove Co., 484 A.2d. 1234, 1240 (N.J. 1984). For the purposes of strict liability, the Brown court limited "substantial" to mean that it must directly affect the safety of the product and its potential to cause danger. But see Glassey v. Cont'l Ins. Co., 500 N.W.2d 295, 303 (Wis. 1993) (holding in situations where product has undergone substantial change by third party, compensation for injury is better served by common law negligence theory).
76 Wheeler v. Andrew Jergens Co., 696 S.W.2d 326, 328 (Ky. Ct. App. 1985) (stating manufacturers' failure to implement safety features on shampoo bottles to prevent tampering before placing into stream of commerce could constitute design defect).
77 James A. Lowe & Mark L. Wakefield, AM. LAW OF PROD. LIAB. § 69.41 (3d ed. 2004). Self-imposed standards within an industry generally originate out of a concern for consumer safety when a particular product has a widely recognized capability to cause harm. Id.
78 Uniroyal Goodrich Tire Co. v. Martinez, 977 S.W.2d 328, 337 (Tex. 1998) (holding widespread use of advanced safety technology within industry is a consideration in assessing liability). Uniroyal Goodrich Tire Company ("Goodrich") learned this lesson in the early 1990's when a tire it manufactured exploded, causing severe injury to a mechanic attempting to mount the tire to a car. Id. at 331-32. In 1990, Goodrich employed a tire design that most of Goodrich's competitors had abandoned by the early 1980's in favor of a safer alternative. Id. at 337. The court considered Goodrich's prior knowledge of and failure to employ a safer alternative that was available and widely used by the industry in its decision to deny a motion for rehearing after a jury found Goodrich liable. Id.; see also Martin v. Michelin N. Am., Inc., 92 F. Supp. 2d 745, 753 (E.D. Tenn. 2000) (holding plaintiff made out prima facie case of products liability for Michelin's failure to employ the single strand bead tire design, regardless of whether it knew the technology existed, because it could have known a safer alternative existed and that competitors employed such design). The plaintiff's injuries were caused by an exploding tire under nearly identical facts to Goodrich. Id. at 747. Michelin manufactured the tire in 1990. Id. at 749.
safer design or technology. The simple fact that a small segment of an industry employs a safer design is typically insufficient to determine that all those who fail to employ the technology operate below the industry standard. A single industry leader, however, has successfully created higher industry standards by implementing safer components in a product.

The liability of pharmaceutical manufacturers for unsafe products has yet to be tested substantially under design defect theory. In one of the few challenges on record, the manufacturer prevailed. The Fagan decision, however, does not necessarily insulate manufacturers from future liability because a plaintiff need not demonstrate that packaging is completely tamper-proof to prove that a packaging design is unreasonably susceptible to tampering. Counterfeit and tamper resistant technologies, even if not

80 See Alevromagiros, 993 F.2d at 422.
81 Cheryl Lynn Daniels, Note, The Seatbelt Defense and North Carolina's New Mandatory Usage Law, 64 N.C. L. REV. 1127, 1131 (1986). In the 1950's Ford Motor Company began installing seatbelts in all of its cars and encouraged its domestic competitors to follow its lead. Id. Within a decade of Ford launching its crusade, the automotive industry's self-imposed safety precautions led to an elevated level of care to which manufacturers continue to be held as various jurisdictions began to require seatbelts in cars. Id. Today, every state law requires that cars come equipped with seatbelts. Id.
82 See Fagan v. AmerisourceBergen Corp., 356 F. Supp. 2d 198 (E.D.N.Y. July 29, 2004), remanded by No. 05-1843, 2006 LEXIS 2117 (2d Cir. Jan. 19, 2006) (granting pharmaceutical manufacturer's motion to dismiss negligence claim that alleged injuries were caused by its failure to employ more effective tamper-proof technologies). The Court dismissed the claim against Amgen, a major pharmaceutical manufacturer, reasoning that the plaintiff's claim was essentially that the defendant's packaging was not "tamper-proof enough," and that plaintiff could not establish how it was feasible for Amgen to design its product in a safer manner. Id. at 206-07. In dismissing the action, the court held that the plaintiff had no claim because no packaging is completely tamper-proof. Id. The court reasoned that even though Amgen's failure to employ safer packaging technology might create a likelihood of harm to a consumer in the plaintiff's position, the plaintiff was unable to prove that the packaging created a "substantial likelihood of harm." Id.
83 See RESTATEMENT (THIRD) OF TORTS § 2(b) (1998) (stating "a product . . . is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe." (emphasis added)). While design defect liability does not rise to a level that would require a drug manufacturer to design a product that is "excessively safe," the rational behind limiting design defect liability is to prevent careless consumers from benefiting to
one hundred percent fool-proof, may be sufficiently fool-proof to thwart counterfeiting, and as such, are sufficient to prevent consumers from suffering harm as a direct result of unknowingly using a counterfeit or adulterated product.84

Manufacturers also can be held strictly liable for failure to warn of dangers posed by their products.85 Thus far, courts have been reluctant to impose a duty on pharmaceutical manufacturers to warn consumers that product packaging is susceptible to criminal tampering.86 Likewise, no duty has been imposed upon manufacturers to anticipate tampering and take steps to prevent tampering in product design.87 These rulings, however, emphasize important qualifications.88 Additionally, a manufacturer is the detriment of careful consumers. RESTATEMENT (THIRD) OF TORTS § 2, cmt. a. “From a fairness perspective, requiring individual users and consumers to bear appropriate responsibility for proper product use prevents careless users and consumers from being subsidized by more careful users and consumers, when the former are paid damages out of funds to which the latter are forced to contribute through higher product prices.” Id. Because even the most careful consumer is susceptible to injury caused by counterfeit drugs the issue is not whether the reasonable alternative design is 100% safe, but whether a safer design could have reduced or prevented any resulting injuries. Id.

84 RESTATEMENT (THIRD) OF TORTS § 2(b) and cmt a.
85 See RESTATEMENT (SECOND) OF TORTS: EFFECT OF WARNING § 301 (2005) (issuing a warning does not necessarily absolve one from liability); see also RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM § 18 (Proposed Final Draft 2005).
86 Elsroth v. Johnson & Johnson, 700 F. Supp. 151, 167-68 (S.D.N.Y. 1988). The court held the manufacturer of over-the-counter medication was not liable for criminal tampering with a drug that caused a consumer’s death subsequent to the medication leaving the manufacturer’s control. Id.
87 See Elsroth, 700 F. Supp. at 161. In a clear example of the inadequacy of federal regulation in this area, the court considered that the manufacturer’s packaging employed three of the tamper-proof features recommended by the FDA when forming its decision that the manufacturer was not negligent. Id. Note, however, that the court did not decide whether there was a design defect in Johnson & Johnson’s product, but instead refused to find Johnson & Johnson liable because evidence demonstrated that no packaging could have prevented the kind of sophisticated tampering that occurred in this case. Id. at 160-61. In fact, the court held “although masquerading as a claim for ‘better protection against tampering,’ it is, in reality, a claim for tamper-proof packaging. Unfortunately, no such packaging exists.” Id. at 161. The premise of this note, however, is that the technology does in fact exist, or at the very least, technology exists which is so difficult and expensive to counterfeit that it would deter counterfeiters from attempting to tamper with or counterfeit a product. See discussion infra Part IV.
88 Elsroth, 700 F. Supp. at 165 (holding manufacturer had no duty to make Tylenol only in tablet form when it was well known and recognized that gel capsules were more prone to tampering, “especially when those capsules are sold with a feature (state-of-the-art, tamper-resistant packaging which minimizes the criminal risk”). The court also reasoned that the plaintiff introduced no evidence that safer packaging was available and could have been employed. Id. at 165-66. The doctrine of strict liability was not created to hold manufacturer’s accountable for the
not liable under failure to warn theory for defects of which it does not know or were not
knowable. Counterfeiting and tampering of pharmaceutical and biomedical products,
however, is widespread, thereby rendering the danger to consumers to be not only
"knowable," but also foreseeable.

B. The Learned Intermediary Doctrine

A manufacturer of prescription drugs is generally free from liability for injuries
to patients caused by inadequate warnings directed at consumers. This rule is rooted
in policy considerations fearing that judicially imposed liability would discourage the
development of medical technology. The Learned Intermediary Doctrine rests on the
theory that it is the patient’s prescribing physician, not the manufacturer, who is in the
best position to educate the patient of the risks presented by a drug given the patient’s
specific medical condition and therapeutic needs. Despite this general rule, the trend
in the law is to back away from this blanket immunity afforded to pharmaceutical
manufacturers and, where appropriate, impose a direct duty on the manufacturer to
warn patients. This duty logically extends to situations in which the patient is able to
bypass the physician and obtain the medication on his own. Additionally, advertising
drugs in the mass media may open the door to manufacturer liability for patient
injuries. Therefore, the immunity once enjoyed by drug manufacturers is not

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90 See supra notes 2, 48 and 59. Repeated cases of counterfeiting combined with Congressional
and private industry focus on counterfeit resistant technologies is evidence that the problem of
2004), remanded by No. 05-1843, 2006 LEXIS 2117 (2d Cir. Jan. 19, 2006); Pharmaceutical Market
Access Act of 2005, H.R. 328, 109th Cong. § 6 (2005); Reducing Fraudulent and Imitation Drugs
91 RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d)(1) (1998) (directing the
manufacturer’s duty to warn to the physician, who in turn must disclose risks of the drug to the
patient, rather than a direct obligation on the manufacturer to warn the patient). This notion is
popularly known as the Learned Intermediary Doctrine. Id.
92 See Id. cmt. b (explaining the rationale and historical significance of the Learned Intermediary
Doctrine).
93 Id.
94 RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d)(2), cmt. b (1998) (suggesting a
duty to warn when manufacturers know or have reason to know that health-care providers are
not in a position to reduce the risk of injury).
95 Id. at cmrt. e. The requirement of direct warnings and instructions to patients is justified where
a health-care provider is not an intermediary, and the supervision that ordinarily accompanies the
prescription process thus does not exist. Id.
96 Id. There exists disagreement regarding whether adequate warning to health-care providers

necessarily warranted in today’s marketplace, especially given the manufacturers’ knowledge that their products are susceptible to counterfeiting and tampering, and that no other individual or entity is in better position to protect the consumer from the resulting injuries.

C. Products Liability: Traditional Negligence Theory

The fact that the majority of industry members do not employ a particular safety precaution is not dispositive of the reasonability of a practice. The seminal case imposing negligence liability for the failure to employ a reasonably available safety alternative makes it clear that companies will bear the responsibility of employing available safety alternatives where such alternatives exist. In *The T.J. Hooper*, a tugboat company failed to employ available and reasonable safety alternatives when it did not use radios on its tugs which would have alerted the crew to a storm and provided ample time to seek refuge. As a result, the tugs and the barges towed by the tugs were lost at sea and eventually sank. The tug company was held liable to the cargo owners for the value of the lost cargo. The court held that the tug company had a duty to install readily available radios in its boats, that failing to do so was a breach of that duty, that the failure to have radios onboard was the but for cause and the proximate cause of the boats and cargo being lost at sea, and that the cargo owners suffered damage as a result of the loss of their goods. In this case, the mere existence of an available safety alternative that the company failed to employ was sufficient to establish the standard to which the entire shipping industry would be held. This situation bears resemblance to the current climate within the biomedical industry in which reasonable safety precautions are not employed despite manufacturers’ knowledge that these counterfeit

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satisfies the federal requirement that drugs advertised directly to patients through the mass media must be accompanied by the appropriate warnings and instructions. *Id.*

97 See generally *The T.J. Hooper*, 60 F.2d 737 (2d Cir. 1932).

98 *T.J. Hooper*, 60 F.2d at 740 (holding tug boat company’s failure to use radios unreasonably dangerous considering their ready availability and the high degree to which the radios enhanced safety). The court noted that a “whole calling may have unduly lagged in the adoption of new and available devices.” *Id.* at 740. “[T]here are precautions so imperative that even their universal disregard will not excuse their omission.” *Id.* Therefore, although no law mandated the presence of the safety equipment, and there existed no industry custom to employ such equipment, it was found to be so reasonably available that any prudent member of the industry ought to have employed it. *Id.*

99 *T.J. Hooper*, 60 F.2d at 737.

100 *Id.* at 738.

101 *Id.* at 737.

102 *Id.* at 740.

103 See *T.J. Hooper*, 60 F.2d at 737.
resistant technologies exist and are available for implementation.

IV. Legal Implications of Emerging Counterfeit-Resistant Technologies

The pharmaceutical industry’s increased effort to discover and employ more effective counterfeit resistant technology results from two motivating factors. First, counterfeit drugs present significant health and safety risks to patients who believe they are taking the real drug. Second, masterfully replicated fake drugs infiltrate legitimate distribution channels and travel to consumers without detection, causing negative publicity and a diminished product image. The result of these situations is foregone revenue that would have been generated from sales to consumers who unknowingly bought fake drugs while intending to buy the real product, as well as lost sales to consumers who may refuse to buy a drug after losing faith in a company’s ability to secure the safety of its products. Pharmaceutical companies’ financial incentives to invest in new technology will likely have significant legal implications for the industry.

A. Strict Tort Liability

Drug manufacturers clearly recognize the importance and necessity of counterfeit-resistant technology, as is made evident through the increase in research and development in the area. A company generally will not incur the expense of modifying a product design or the expense of researching methods to modify a design unless its own risk-utility analysis indicates that such modification is financially advantageous.

The first factor to consider in determining whether a product design is unreasonably dangerous is the product’s usefulness and desirability. FDA approved pharmaceuticals are the life blood of drug manufacturers; the steep prices of pharmaceutical products reflect not only the high costs of production, but also the strong demand for these products in the marketplace. Conversely, high demand for a

\[\text{Butalla, supra note 16.} \]
\[\text{See supra notes 32 and 34 and accompanying text.} \]
\[\text{Am. LAW OF PROD. LIAB., supra note 71.} \]
\[\text{See supra note 71.} \]
\[\text{Rother, John, Director of Policy and Strategy for American Association of Retired Persons,} \]
drug is evidence of its usefulness and desirability because demand is significantly less for drugs that fail to produce desired results. Furthermore, the FDA will only approve a product after evaluation of the product's efficacy and safety, factors which measure a product's "usefulness." Therefore, FDA approved products, are inherently, by their very nature, desirable and useful.

Secondly, in examining a defective design analysis it is essential to consider the safety features of the product. While the chemical composition of FDA approved pharmaceuticals is generally safe, a product's susceptibility to counterfeiting or tampering can render it unreasonably dangerous. Available product safety features range from RFID technology, electrostatic design, holograms, and color-shifting ink, to more limited safeguards such as shrink-wrapped packaging. Many companies use only minimal safeguards to protect from counterfeiting and tampering despite the availability of technology that would better protect their products. Such companies are on notice that existing technology could give rise to alternative product designs that enhance product safety.

Another factor in the design defect analysis is the manufacturer's ability to correct the safety deficiency without diminishing the product's efficacy or rendering the product too expensive. Counterfeit resistant technology affects physical attributes of a product or its packaging, but not the chemical composition or any other property
related to the actual efficacy of a product.\textsuperscript{118} The cost of implementing alternative safety features, however, is the manufacturers' traditional argument against employing counterfeit resistant technology.\textsuperscript{119} Although the cost of the technology presents a strong argument against requiring counterfeit resistant technology, members of the industry have voluntarily begun implementing such programs, which indicate that the marginal cost of employing such technology can be mitigated and outweighs the potential risk posed by legal liability.\textsuperscript{120}

While the cost of developing and implementing counterfeit resistant technology may be high, that cost decreases with more widespread use of the technology.\textsuperscript{121} For instance, RFID technology, created in the 1940's, has advanced over time to make the application considerably less expensive and far more accessible to companies with smaller budgets.\textsuperscript{122} As voluntary use of counterfeit resistant technology becomes commonplace in the drug industry, and consequently decreases the cost of implementing the technology, history indicates that widespread use will create new legal standards.\textsuperscript{123}

A manufacturer will also consider the consumer's ability to avoid harm by using the product carefully.\textsuperscript{124} A consumer's ability to avoid the danger of counterfeit or adulterated drugs is minimal, however, because the fakes are nearly impossible to detect.\textsuperscript{125} Moreover, pharmaceutical products generally are limited in how they can be administered, whether by ingesting orally, applying to skin, injecting by syringe, or any other alternative.\textsuperscript{126} In each case, the manner of consumption of a particular drug varies little from consumer to consumer, and unlike operating dangerous machinery,

\begin{flushleft}{\textsuperscript{118} See supra notes 26 and 28.} \end{flushleft} \begin{flushleft}{\textsuperscript{119} See Gardiner Harris, \textit{Tiny Antennas to Keep Tabs on U.S. Drugs}, \textit{N.Y. Times}, Nov. 15, 2004, at A1 (reporting that expense of RFID technology will include a cost of between $.20 to $.50 per label plus accompanying readers and scanners at a cost of thousands of dollars).} \end{flushleft} \begin{flushleft}{\textsuperscript{120} See \textit{A.M. LAW OF PROD. LIAB.}, supra note 71.} \end{flushleft} \begin{flushleft}{\textsuperscript{121} See \textit{RFID Streamlines Processes, infra note 122.} \end{flushleft} \begin{flushleft}{\textsuperscript{122} RFID Streamlines Processes, Saves Tax Dollars, available at \url{http://www.sun.com/br/-government_1216/feature_rfid.html} (last visited September 20, 2006). Sun Microsystems' corporate webpage describes the historical uses of radio frequency identification technology and the successive improvements to RFID that have driven down its cost and led to widespread use of RFID across several governmental agencies and private industries. \textit{Id.}} \end{flushleft} \begin{flushleft}{\textsuperscript{123} See generally Uniroyal Goodrich Tire Co. v. Martinez, 977 S.W.2d 328 (Tex. 1998).} \end{flushleft} \begin{flushleft}{\textsuperscript{124} See \textit{A.M. LAW OF PROD. LIAB.}, supra note 71.} \end{flushleft} \begin{flushleft}{\textsuperscript{125} See supra notes 20, 22 and 33 and accompanying text.} \end{flushleft} \begin{flushleft}{\textsuperscript{126} See Vogelson, Cullen T., \textit{Advances in Drug Delivery Systems} (discussing various methods to administer drugs) available at \url{http://pubs.acs.org/subscribe/journals/mdd/v04/i04/html/-MDD04FeatureVogelson.html} (last visited September 20, 2006).} \end{flushleft}
consumers of pharmaceutical products generally already use the products as carefully as possible.\textsuperscript{127} Therefore, enhanced safety features, either on the product itself or in packaging, which verify the source and contents of the product, are all the more necessary.

Another factor is the consumer's knowledge of the potential danger posed by the product based on the general public knowledge of the danger and manufacturer's warnings.\textsuperscript{128} Counterfeit and adulterated pharmaceutical products are nearly identical to the authentic products and are indistinguishable to the average consumer.\textsuperscript{129} Consumers therefore have no choice but to trust that the drugs they receive from retail pharmacies are the same drugs shipped from the manufacturer.\textsuperscript{130} Even with universal public knowledge of the dangers posed by counterfeits, in the absence of clear counterfeit resistant technology that verifies authenticity, a consumer remains at risk of unknowingly acquiring and consuming a harmful fake.\textsuperscript{131} Therefore, even extreme consumer vigilance may not prevent injuries caused by fake or adulterated products.

The analysis of the seven factors, listed above, weighs against the manufacturers. In summary, manufacturers place consumers at risk by failing to implement counterfeit resistant technology that renders products safer, manufacturers currently have access to safer technology, manufacturers will likely further develop counterfeit resistant technologies in an effort to protect the integrity of their blockbuster products, and the expense of implementing these technologies can be overcome or outweighed by legal and financial considerations.\textsuperscript{132}

After considering the above seven factors, however, a plaintiff still must prove foreseeability of injury caused by a design defect.\textsuperscript{133} A company is compelled to adhere to that standard to which all reasonable members of the industry follow, and any

\textsuperscript{127} See Martin, supra note 78, at 748 (discussing proper precautions taken by plaintiff in order to minimize danger posed by inherent safety hazards of mounting tires).
\textsuperscript{128} See AM. LAW OF PROD. LIAB., supra note 71.
\textsuperscript{129} See supra notes 20, 22 and 33 and accompanying text.
\textsuperscript{130} See generally Masland, supra note 20 (acknowledging that fake drugs can enter legitimate distribution channels and make their way to pharmacies). Certainly, when products are purchased over the internet and the source cannot be definitively identified, the consumer increases the risk of acquiring unsafe products. See Peter J. Pitts, \textit{Pharmaceutical Fakeery Is Healthcare Terrorism}, BALTIMORE SUN, Aug. 15, 2006, at 11A.
\textsuperscript{131} See supra notes 20, 22 and 33 and accompanying text.
\textsuperscript{132} See AM. LAW OF PROD. LIAB., supra note 71.
\textsuperscript{133} See AM. LAW OF PROD. LIAB., supra note 71.
deviation from that standard may amount to a breach of its duty to consumers. As the prevalence of counterfeit and adulterated drugs continues to increase, the foreseeability of unsuspecting consumers suffering injury is increasingly more likely. Likewise, existing counterfeit-resistant technologies render it entirely foreseeable that additional advances in security will emerge and enhance the capabilities of pharmaceutical manufacturers to safeguard drugs against counterfeiting. Moreover, the technologies will likely become more affordable, thus making it more feasible for drug manufacturers of all financial size and strength to employ some level of technology. Therefore, when a pharmaceutical company fails to employ counterfeit resistant technology, the company may breach its duty to the consumer.

B. Analysis of the Learned Intermediary Doctrine

The Learned Intermediary Doctrine intends to shield manufacturers from liability arising out of the health risks presented to a patient by a product’s chemical composition. Broadly construed, manufacturers could attempt to argue that the doctrine insulates them from liability associated not only with the health risks a product’s composition may present, but also by the risks associated with ingesting a counterfeit product. This argument, however, fails to acknowledge the premise of the doctrine because a doctor is not in a better position, but is in fact in a worse position than the manufacturer to convey the risks of using counterfeit and adulterated products. Additionally, the rationale that government regulatory bodies effectively

134 Restatement (Second) of Torts: Misrepresentation by Sellers of Chattels to Consumer § 402B (1965).
135 See Bill to Fight Counterfeits Would Require RFID Tags for All Drugs, FDA Week, Mar. 3, 2006 (reporting World Health Organization predicts percentage of counterfeit pharmaceuticals will double by 2010).
136 See Giuliani Partners, supra note 24 (discussing various counterfeit-resistant technologies in development).
137 See RFID Streamlines Processes, supra note 122 (demonstrating how cost of technology decreases with time).
138 See supra notes 91 and 92.
139 See supra notes 91 and 92.
140 Restatement (Third) of Torts: Products Liability § 6(d)(1) (1998). The premise of the Learned Intermediary Doctrine is that a physician is in the best place to warn a patient about specific risks of a prescription drug because the physician can take into account the drug’s active ingredients and potential side effects in conjunction with the patient’s specific medical history. In the case of counterfeit drugs where the danger is unknown to the physician and no amount of education will enable the physician to adequately inform or warn a patient of risks the physician cannot discover, there is no “learned intermediary” between the drug manufacturer and the consumer. Consequently, the Doctrine should not operate to relieve the drug
screen all new drugs and prevent dangerous pharmaceuticals from reaching consumers applies primarily to the chemical qualities of a drug and not to a product's susceptibility to counterfeiting. Therefore, the doctrine is not applicable to potential liability arising from counterfeit drugs.

In the event that courts would determine that the doctrine does in fact insulate manufacturers from liability attributable to counterfeit and adulterated products, manufacturers still are not free from potential liability. By launching massive advertising campaigns directly targeting consumers, the pharmaceutical and biotech industries have perhaps pierced the shield from liability afforded by the Learned Intermediary Doctrine because patients now receive information about drugs not only from their physicians, but also directly from the manufacturers. Therefore, in circumventing the intermediary who previously disseminated all information relating to a drug and its possible risks, drugs manufacturers have intentionally communicated information to patients, which may open the door to liability.

C. Products Liability: Traditional Negligence

Case law arising out of other industries provides clear examples of the potential liability facing pharmaceutical and biotech manufacturers. As more companies employ technology to safeguards their drugs, the more likely it becomes that a higher standard of care will emerge and expose companies that opt not to pursue anti-counterfeiting technologies to liability. The T.J. Hooper highlights how negligence liability can develop out of trade custom and how the government need not intervene with specific legislation before a heightened standard of care emerges to which a company can be held.

An analysis of the traditional elements of tort law reinforces this assertion. A company is compelled to adhere to that standard to which all reasonable members of the industry follow, and any deviation from that standard may amount to a breach of their duty to consumers. The current focus of developing counterfeit-resistant

manufacturers of liability. Id.

142 See supra notes 95 and 96.
143 See supra notes 95 and 96.
144 See supra note 97 and accompanying text.
145 See supra note 97 and accompanying text.
146 See supra note 97; see also Daniels, supra note 81.
147 RESTATEMENT (SECOND) OF TORTS: MISREPRESENTATION BY SELLERS OF CHATTELS TO CONSUMER § 402B (1965).
technologies renders it foreseeable that pharmaceutical and biotech manufacturers will continue to invest in anti-counterfeiting technologies. As such technology becomes more readily available it will be more financially feasible for manufacturers to employ counterfeit resistant technology. As technology becomes more affordable, it will be more reasonable for companies to use the technology and more unreasonable for companies not to implement it. Therefore, as more pharmaceutical manufacturers employ counterfeit resistant technology, the failure by other pharmaceutical companies to use these technologies may very well constitute a breach of their duty to consumers.

The key factor to analyze under traditional tort liability theory is causation. When a company continues to use a technology known to leave tires susceptible to explosion, and a safer feasible alternative exists at the time a tire explodes, a direct causal link exists between the company’s failure to manufacture a safe tire and the consumer’s injury. However, the very nature of counterfeit pharmaceuticals requires an intervening cause to occur when a third party creates a drug that closely resembles the real drug, but does so without the consent of the licensed manufacturer. Modern tort negligence law recognizes that causation can stretch to third party intervener such that their actions are not so unforeseeable as to constitute a superseding cause. Just as it is entirely foreseeable that a shampoo bottle could be tampered with after leaving the manufacturer and prior to purchase, it is likewise entirely foreseeable that a drug produced or packaged with ineffective controls to prevent tampering or to distinguish it from counterfeits could cause harm when an unsuspecting patient takes the drug, believing it to be legitimate. Therefore, the intervening counterfeiter may not be a superseding cause of any injury resulting from consumption of a counterfeit drug.

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148 See Giuliani Partners, supra note 24 (discussing various counterfeit-resistant technologies in development).

149 See RFID Streamlines Processes, supra note 122 (demonstrating how cost of technology decreases with time).

150 See supra note 97.

151 See supra note 97.


153 RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM § 29, (Tentative Draft No. 3, 2003); see generally Uniroyal Goodrich Tire Co. v. Martinez, 977 S.W.2d 328 (Tex. 1998).

154 See RESTATEMENT, supra note 134.

155 Wheeler v. Andrew Jergens Co., 696 S.W.2d 326, 328 (Ky. Ct. App. 1985) (third party tampering with shampoo bottle is foreseeable and may not constitute intervening and superseding cause of injury such that manufacturer is absolved from liability).

156 Id.

157 See Jergens, 696 S.W.2d at 328.
As a result, those manufacturers who opt not to invest in counterfeit resistant technology may find that this failure to act is not only a breach of their duty to consumers but also the proximate cause of any resulting injury. Such duty, breach of duty, and proximate causation could expose manufacturers to potential negligence liability. Moreover, even if the industry does not implement much of the experimental counterfeit-resistant technology, the acts already undertaken to conduct and finance numerous studies in order to reduce the dangers of counterfeit and adulterated products may be sufficient to demonstrate knowledge of a product's danger, and consequently pave the way for imposition of a higher standard.

V. Conclusion

Pharmaceutical and biomedical manufacturers who choose not to incorporate counterfeit-resistant technology to distinguish their products from counterfeits leave their products more susceptible to counterfeiting. While one group of patients may be adequately protected because their prescription drug manufacturer employs the latest counterfeit proof technology, another patient group may be at great risk of injury because the manufacturer of their drug of choice has neglected to use equivalent technology. Accordingly, drugs not protected by counterfeit-resistant technology are most likely to be counterfeited, and consumers who use unprotected medications will be most susceptible to receiving counterfeits and most susceptible to injury. The existence of counterfeit resistant technology may soon impose a new and heightened duty upon manufacturers to employ such technology to protect consumers, and failure to implement the technology, regardless of the cost of doing so, may soon be a breach of duty to consumers and a foreseeable cause of consumers' injuries.

158 Id.
159 Id.
160 JAMES A. LOWE & MARK L. WAKEFIELD, AM. LAW OF PROD. LIAB. § 69.37 (3d ed. 2004). Corporate libraries contain documents of studies financed by industry groups which can indicate a company's awareness of its product's potential for harm at the time of manufacture and sale. Id.