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Bryan A. Liang

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Parallel Trade in Pharmaceuticals: Injecting the Counterfeit Element into the Public Health

Bryan A. Liang†

ABSTRACT
Varying prices for medicines create incentives to move products from one market to another in an effort to arbitrage the difference; this is known as parallel trade. Nevertheless, this situation allows nefarious individuals to introduce counterfeits into the drug supply due to weaknesses in detection. Both developed and developing countries around the world experience this phenomenon. The United States has so far been relatively insulated from such effects, but through potential legalized importation and illegal parallel trade through Internet purchases, the risk that the European Union has experienced may threaten the United States. Unfortunately, efforts to permit parallel importation of drugs into this country, such as under the Pharmaceutical Market and Drug Safety Act, do not adequately address safety and security issues of parallel trade. The vulnerabilities of the U.S. system, and the lessons from regions such as the European Union which has permitted parallel trade in pharmaceuticals, indicate that a multidisciplinary policy strategy involving at least a public health campaign, reporting system, increased penalties for counterfeiting, and technology investment must be engaged before any parallel trade in medicines is permitted. Otherwise, the safety and security of the U.S. medicine supply will assume the weaknesses and risk that other regions experience.

† Executive Director and Professor of Law, Institute of Health Law Studies, California Western School of Law; Co-Director and Adjunct Associate Professor of Anesthesiology, San Diego Center for Patient Safety, University of California, San Diego School of Medicine; Adjunct Associate Professor of Public Health, College of Health and Human Services, San Diego State University; and Adjunct Professor of Aviation, College of Aviation, Western Michigan University. Professor Liang also serves on the Board of Directors of the Partnership for Safe Medicines. B.S., MIT; Ph.D., University of Chicago, Harris School of Public Policy Studies; M.D., Columbia University, College of Physicians & Surgeons; J.D., Harvard Law School.
I. Introduction

The cost of prescription drugs is a critical issue faced by many around the world. Prices are very high in some markets, but less
so in others. There are strong incentives for moving drugs from one market to another, usually across country borders, to take advantage of price differentials, that is, parallel trade. Although some would perform this arbitrage activity legally, such price differentials also create incentives for unethical actors to enter into the market of parallel trade in order to introduce tainted and counterfeit drugs. This occurs all over the world in developed nations, particularly in the European Union, which has permitted parallel trade for some time. These dishonest players peddle fakes through vulnerabilities in the drug distribution system.

In the United States, counterfeits are a growing problem, but our domestic, closed system has so far maintained a high level of safety. However, the United States faces a similar downside potential for parallel importation as experienced by the European Union since Congress is considering permitting medicine importation. Without extensive new infrastructures involving safety systems, stakeholder awareness of the problem, robust reporting systems, appropriate laws and regulations, investment in technology, and coordination of these components, parallel drug importation into the United States could very well open U.S. borders to tremendous problems with fakes, creating harm, supporting crime, and reducing the benefits associated with advances in pharmaceuticals.

This paper reviews some of the issues associated with parallel trade, counterfeit drugs, and drug importation. In Part I, this paper


2 U.S. DEP’T OF HEALTH AND HUMAN SERVICES, HHS TASK FORCE ON DRUG IMP.: REPORT ON PRESCRIPTION DRUG IMPORTATION 37-38 (Dec. 2004), http://www.hhs.gov/importtaskforce/Report1220.pdf [hereinafter TASK FORCE]. Note that the only parties that can legally parallel import drugs for domestic use are the manufacturers themselves. Id.

reviews the European experience with respect to parallel trade. In Part II, the U.S. system is considered. In Part III, rationales underlying counterfeit production within the parallel trade system are outlined. In Part IV, the 109th Congress importation bill, the Pharmaceutical Market Access and Drug Safety Act, also known as the Dorgan Drug Importation Bill, is reviewed. In Part V, a multidisciplinary proposal is offered that would allow a better understanding of the burdens of counterfeit drugs and means to counteract them. Finally, in Part VI, the paper offers some recommendations to prevent the influx of counterfeits into the drug supply.

II. The European Experience: Parallel Trade and Counterfeits

Although counterfeit problems are not well known in the United States, they are common throughout the rest of the world.  

4 "When people [in the United States] think of counterfeits, they don't usually think pharmaceuticals... [But] a[n] entire range of products are counterfeited and some of them produce obvious health and safety issues.” Don Oldenburg, Raising the Alarm on Counterfeit Drugs, WASHINGTON POST, Apr. 5, 2005, at C9 (quoting Darren Pogoda, Staff Attorney, International Anti-Counterfeiting Coalition). Note, however, that U.S. citizens may be traveling to countries that have a high level of counterfeits. For example, there is a growing trend of Americans and others obtaining health care in India. See, e.g., Ramola Talwar Badam, Westerners Seek Cheap Medical Care in Asia, S.F. CHRON., Sept. 24, 2005, http://www.sfgate.com/cgi-bin/article.cgi?file=/n/a/2005/09/24/international/i130437D67.DTL&type=printable.

International drug counterfeiting is due, in part, to the presence of parallel trade. In medicines, this can be illustrated by international drug importation and re-importation in and between Europe and other countries around the world.

A. Incentives

The incentive to engage in drug counterfeiting is attributable in part to differences in medicine pricing among European countries, and is permitted in the European Union under Article 28 and Article 81 of the European Commission Treaty for the Free Movement of Goods and Services within the Internal Market of

Tragically, although all persons are potentially affected by counterfeit drugs, at present, according to the World Health Organization, the poor are more susceptible to fake drugs than other populations. See WHO Warns the Poor are Increasingly at Risk from Counterfeits, SAFEMEDS WEEKLY NEWS UPDATE, Sept. 30, 2005, http://www.safemedicines.org.

6 See World Health Org., Essential Drugs and Medicines Policy (June 28, 2004), http://www.who.int/countries/eth/areas/medicines/en/index.html. Because of significant price differentials, "hugely divergent prices exist . . . which in turn allows counterfeit products to be introduced." Id. See Global Forum on Pharmaceutical Anticounterfeiting Calls for Increased Corporate Responsibility and a Framework Convention, eMEDIA WIRE, Mar. 21, 2005, http://72.14.203.104/search?q=cache:082pF3YBUekJ:www.pharma-anticounterfeiting.info/files/uploadedfiles/674/ForumMediaAlertMar05.doc+Global+For um+on+Pharmaceutical+Anticounterfeiting+Calls++for++Increased++Corporate++Res ponsibility++and++a++Framework++Convention,&hl=en&gl=us&ct=clnk&cd=1&client =safari (describing Second Global Forum on Pharmaceutical Counterfeiting, Paris, France, and policy statements emanating from it). For example, Switzerland has been subject to at least two major cases of counterfeit drug trafficking over the past three years; in response, it has convened a Council of Europe meeting on the topic sponsored by the Swiss Agency for Therapeutic Products (Swissmedic); Matthew Allen, Switzerland Joins Fight Against Fake Drugs, SWISINFO, Sept. 20, 2005, http://www.nzz.ch/2005/09/20/eng/article6099293.html. Note also that the European Union has had similar problems with foodstuffs representing a very similar process as counterfeit drugs. For example, Switzerland and Ireland have reported illegally imported foods that are linked to organized crime and unsafe product conditions. See, e.g., Adam Beaumont, Illegal Meat Trade Sparks Health Fears, NZZ ONLINE (May 23, 2005), http://www.nzz.ch/2005/05/23/eng/article5799697.html; Illegal Food Import Seizures Rise, BBC NEWS, May 25, 2005, http://news.bbc.co.uk/2/hi/uk_news/northern_ireland/4579099.stm.

Of course, other parts of the world beyond Africa, Europe, and Asia have been affected, such as Australia. See Pan Can't Pay $3m Fine; Liquidator, SYDNEY MORNING HERALD, Dec. 13, 2005, http://www.smh.com.au/news/National/Pan-fined-3m-over-counterfeit-drugs/2005/12/13/1134236045453.html (reporting pharmaceutical firm in Australia fined $3 million for supplying counterfeit drugs, and has gone into receivership).
the EU countries. This principal of free movement mandates that no country within the European Union may place legal, legislative, or other types of barriers preventing trade between members. Further, an owner of a trademark may not use its rights to prevent repackaging of the medicinal product if the repackaging will not adversely affect the original condition of the product. Hence, through the regulatory system's consent to parallel trade, drugs may pass through many countries and scrupulous and unscrupulous sellers' hands before ending up in a pharmacy.

Under such a rubric, legitimate drugs in route to another market may be replaced with fake, tainted, different, expired, concentrated, or diluted drug forms and/or ineffective materials;
or legitimate drugs (or diluted drugs with active ingredients) may be mixed with counterfeits, a process known as "salting." In the latter effort, even if drug supplies are checked, the actual pharmaceutical ingredient will still be detected, in an effort to fool inspectors, pharmacists, patients, and others into believing the products are legitimate.

It bears emphasis that repackaging drugs is permitted and expected in Europe as well as the United States. The resulting importation, re-importation, repackaging, and reselling between parties can and does allow fake drugs to enter into legitimate country supplies that may be sold in pharmacies and be taken by patients.

use of higher level, stronger antibiotics, which contribute to the increasing resistance of the pathogen. Id. at 44. Incorrect concentrations of drugs have included highly concentrated Botox treatment, which almost killed several patients and the doctors that was administering it, as well as cancer treatments to build up red blood cells that were instead bacterially-contaminated water injected directly into the patient. Id. at 8. Use of nonsterile and/or completely inappropriate materials to mimic the drug is also a source of harm, with materials such as floor wax, boric acid, which is a cockroach-killing agent, toxic yellow road paint, concrete powder, and antifreeze have been documented for use in counterfeit drugs. Id. at 9. The latter killed over 500 children. Id.


See, e.g., Susan Todd, Florida Man Admits Sale of Fake Lipitor, STAR-LEDGER (NJ), Feb. 10, 2005, at 60 (describing Lipitor salting by convicted cocaine traffickers); and Todd Datz, Drug Busters, CSO ONLINE, Nov. 1, 2005, http://www.csionline.com/read/110105/counterfeit.html ("If someone reached into your [potential counterfeit supply] container and took out one Lipitor capsule and tested it, and it turned out to be genuine, it does not mean the rest of the capsules in that container are genuine," quoting James Christian, Chief Security Officer, Novartis).


"Shell pharmacies" have been used to illegally buy and sell drugs, illustrating the ease by which systems may be penetrated for inappropriate means. See, e.g., Denise Kallette, Florida Authorities Arrest 10 in Massive Internet Drug Sweep, ASSOCIATED PRESS, July 15, 2005, http://www.signonsandiego.com/news/nation/20050715-1422-internetdrug-arrests.html (describing Internet pharmacy selling millions of dollars of drugs illegally through shell pharmacies).

World Health Org., Essential Drugs and Medicines Policy (June 28, 2004), http://www.who.int/countries/eth/areas/medicines/en/index.html; see also Evelyn Ring,
B. Examples

There have been significant counterfeit issues in Europe domestically and across international lines relating to parallel trade. Madame Maud de Boer-Buquicchio, Deputy Secretary of the Council of Europe, in her opening speech to the Council of Europe seminar, Counteract the Counterfeiters!, emphasized the significant problem of counterfeit drugs in the European Union:

Let me summarize some facts about the counterfeit medicine situation in Europe:

- WHO estimates that counterfeit medicines make up for 8% to 10% of the European pharmaceutical market and in some countries even as much as 12%.
- Experts are convinced that counterfeiting medicine is on the rise in Europe.
- Counterfeit medicines often appear so like the genuine product that neither healthcare professionals nor patients can detect which is the genuine product before using it. Hence, the patient undergoes the risk of using an ineffective, or less effective or even toxic compound not worth being called a medicine or worth the price the individual or the health-care system pays for it.
- All categories of medicine are profitable targets for counterfeiters—so called life-style medicines as well as essential medicines like antibiotics and insulin.
- Several indicators suggest that organized crime has found a currently lucrative and nearly safe business of counterfeiting medicines to generate resources for other criminal activities. Organized crime puts public health and the health of individual citizens at stake, and aims at creating widespread corruption networks which hinder democratic and economic development and welfare. This also deprives the private sector of legitimate revenue.

Against this background, it is very worrying that there is no recognized central reference point in Europe entrusted with

Counterfeit Drugs Will Kill, Expert Warns, IRISH EXAM'R, Oct. 12, 2005, http://archives.tcm.ie/irishexaminer/2005/10/12/story128556160.asp (“New research shows that one in five Irish people have discovered that on purchase their medicine leaflets are missing, seals are broken, or the medicine is contained in a foreign packaging, all signs that the chemist might have unwittingly sold them counterfeit drugs.”).
surveillance, trend analysis and policy recommendations in the field of counterfeit medicines. This situation helps the counterfeiters who can rely on lacking national and international co-operation information gaps in Europe. Even when they are caught, they far too often get away with administrative fines with no deterrent effect.  

There is good reason for this worry, since examples abound. The U.K. authorities identified and caught a counterfeit manufacturer and supplier capable of producing half a million fakes each day who disseminated those products through parallel trade means across Europe. This case follows several recalls and previous U.K. counterfeit discoveries as well as more recent counterfeits discoveries. These circumstances have resulted in


21 Fake Lipitor has been found in the United Kingdom salted with real Lipitor. See IAN HOLLOWAY, MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY, DRUG ALERT, July 28, 2005, http://www.info.doh.gov.uk/ohm/embroadcast.nsf/fd1653b6e66be59d180256b7900507749/ea8953ce99606f56ee8025704c0050887?OpenDocument; Sam Lister, Heart Pills Taken by Millions Recalled as Fakes Are Found, TIMES (London), July 28, 2005, http://www.timesonline.co.uk/article/0,,2-1713086,00.html (reporting statements by head of intelligence at the Medicines and Healthcare products Regulatory Agency, Nimo Ahmed, indicating the discovery of the counterfeit drugs, which came from outside of the European Union, showed that counterfeit medicines could get into any supply chain, even the United Kingdom's, which is one of the most difficult to penetrate). See also Celia Hall, Internet Fuels Boom in Counterfeit Drugs, TELEGRAPH (U.K.), Aug. 16, 2005, http://health.telegraph.co.uk/news/main.jhtml?xml=/news/2005/08/16/ndrugs16.xml (noting that the Internet has increased counterfeits and “[I]n the past year three counterfeit medicines have reached the public in Britain, having penetrated
calls for heightened efforts beyond the current regulatory safety structure.\textsuperscript{22}

European investigations have determined that:

[parallel] drug importation in Europe has led to a situation where drugs often change hands more than 20 times before reaching their destination, frequently manufactured in one country, shipped to the country in which they were intended to be legitimate pharmacy outlets. They were fake Cialis, a drug for impotence, fake Reductil, a slimming drug, and fake Lipitor, a drug to lower cholesterol.\textsuperscript{22} ); Andrew Jack, \textit{Probe Ordered After Fake Drugs Find}, \textit{FINANCIAL TIMES}, Aug. 16, 2005, http://news.ft.com/cms/s/8d9584c4-0e0e-11da-aa67-00000e2511c8.html (noting that the UK medicines regulator "has launched fresh inquiries into pharmaceutical distributors after discovering a second batch of counterfeit anti-cholesterol drugs in two weeks); Andrew Jack, \textit{Tackling Counterfeiters Who Make Pills in Cement Mixers: As Production of Fake Drugs Rises, There are Calls for Greater Efforts to Counter an Industry that Can Kill}, \textit{FINANCIAL TIMES}, Aug. 16, 2005, http://news.ft.com/cms/s/23796da8-0e0e-11da-aa67-00000e2511c8.html (noting that "The World Health Organi[z]ation and other international bodies have called for greater efforts to tackle a problem which—above all in the developing world—is not only widespread but can be fatal: by failing to give patients the right medicines at best, and killing them outright at worst."); Catherine Humble, \textit{Inside the Fake Viagra Factory}, \textit{TELEGRAPH (U.K.)}, Aug. 22, 2005, http://health.telegraph.co.uk/health/main.jhtml?xml=/health/2005/08/23/nviag21.xml (describing another discovery of fake Viagra and unsanitary conditions for production of counterfeit medicines).


Parallel trade business is deceptively easy to set up and create, illustrating the highly vulnerable nature of the drug supply in sectors that allow it. In a recent exposé, a fake parallel trade business was set up with empty cardboard boxes and a single refrigerator in the United Kingdom. The business then obtained a parallel trade license, and contracted with a subsequently convicted known pharmaceutical counterfeiter for supplies. This entity then obtained agreements to sell to pharmacies and hospitals. The television program was "Tonight with Trevor McDonald: Is Your Medicine Fake?", (ITV Broadcast Jan. 9, 2006).
marketed, bought and sold there by wholesalers and then moved yet again to more expensive markets. . . .

[The] United Kingdom . . . imports more prescription drugs than any other nation in the European community. This opened the door for counterfeit and other sub-standard medicines to enter the UK distribution chain. One survey in 2004 revealed that of 300 imported medicines examined, 25% should have failed on ‘safety reasons,’ 50% because of poor quality of product. In addition 80% failed on legal grounds such as intellectual property rights infringement.23

The disadvantages of parallel importation resulting in drug counterfeiting have also affected other European countries. Parallel trade wholesalers in the Netherlands introduced counterfeits into the legitimate supply chain in 2004.24 A licensed Italian pharmaceutical dealer distributed counterfeit gastrointestinal drugs.25 French customs agents seized 542,000 fake drugs in 2003.26

In a particularly heinous discovery, Spanish authorities raided half a dozen laboratories that were producing fake steroids, hormones, and cancer drugs.27 The scope of the activities in the latter operations was astounding: 20,000 fake doses per hour, with thirty million doses and ten tons of high-quality fakes found, as well as vials, capsules, tablets, and doses for injection.28 These illicit products were sold through parallel trade in Italy, France, and Portugal, and more broadly, over the Internet.29

C. Patient Responses

With such extensive and well-publicized seizures across
Europe, patient groups are justifiably alarmed about the implications of the parallel trade situation. As the United Kingdom's Patients Association noted, "We are increasingly concerned not just about counterfeit medicines, but also the growth of unregulated Internet pharmacies, and the patient safety implications of repackaging medicines through parallel trade."\(^3\) A representative from the United Kingdom Centre for Mental Health noted: "We've been saying for some time that parallel trade is the supply chain's soft underbelly, that it is a potential weak spot. Well, given what we've uncovered, you can now remove the word 'potential'; it's a real risk, and it's here now."\(^3\)

The European parallel trade, importation/re-importation situation has been summarized aptly:

> The complex nature of the supply chain across Europe results in some medicines exchanging hands many times before reaching the patient. This creates more opportunities for counterfeit products to enter the supply chain than if the products were sourced nationally. Combined with the accession of ten member states that are significantly poorer than the rest of the EU and that have both current and historic trading ties with the former Soviet Union (where the WHO already estimate the medicine supply chain to contain up to 10% counterfeit product), it is almost inevitable that counterfeit medicines will enter the EU supply chain.\(^3\)

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\(^3\) See Partnership for Safe Medicines, supra note 26 (including a statement by Niall Maclean of the Social Market Foundation noting parallel trade in the European Union). See also Severin Carrell, IOS Investigation: On the Trail of the World-Wide Web of Fake Lifestyle Drugs, INDEP. ON SUNDAY (London), Jan. 18, 2004, at 8 (new E.U. member countries have "long frontiers [that] border countries such as Russia that are notorious for the ready availability of fake drugs."). See also Julian Mount, Diminishing the Risk of Counterfeit Drug, WORLD PHARMACEUTICAL FRONTIERS, http://www.worldpharmaceuticals.net/articles/wpf007_Pfizer.htm. Mount notes that "the website Paypill.com had been found to be selling counterfeit medicines for the second time. Paypill.com has stated, 'We purchase drugs directly from the same parallel imported sources as the NHS, so if we are selling fakes, then the NHS is selling/dispensing fakes too.'" Id. Mount notes that parallel trade also introduces the potential for error at the repackaging
III. United States "Parallel Trade" and Counterfeits

A. Importation: Legal Underpinnings

Parallel trade in the United States is represented by the importation of drugs into the United States from sources outside the country. Currently, however, parallel trade importation of drugs into the United States is illegal. According to the Food and Drug Administration (FDA):

virtually all prescription drugs imported for personal use into the United States from Canada violate the [Federal Food, Drug, and Cosmetics Act (FFDCA)] because they are either unapproved new drugs (21 U.S.C. § 355), labeled incorrectly (21 U.S.C. §§ 352, 353), or dispensed without a valid prescription (21 U.S.C. § 353(b)(1)). Importing a drug into the United States that is unapproved and/or does not comply with the labeling requirements in the FFDCA is prohibited under 21 U.S.C. §§ 331(d), and/or (a). See also 21 U.S.C. §381(a).

FDA approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, packaging location, container/closure system, and appearance. 21 C.F.R. § 314.50. Generally, drugs sold outside of the United States are not manufactured or packaged by a firm that has FDA approval for that drug. Moreover, even if the manufacturer has FDA approval for a drug, the version produced for foreign markets usually does not meet all of the requirements of the United States approval, and thus is unapproved. 21 U.S.C. § 355. The version also may be misbranded because it may lack certain information that is required under 21 U.S.C. §§ 352 or 353(b) but is not required in the foreign country, or it may be labeled in a language other than English (see 21 C.F.R. § 201.15(c)).

Second, with respect to ‘American goods returned,’ it is illegal for any person other than the original manufacturer of a drug to import into the United States a prescription drug that was originally manufactured in the United States and sent abroad (21 U.S.C. § 381(d)(1)). This is true even if the drug at stage, and makes recall difficult when particular problems are identified. Id.
issue were to comply in all other respects with the FFDCA. Importing a drug into the United States in violation of section 381(d)(1) is prohibited under 21 U.S.C. § 331(t).

Thus, to ensure compliance with the FFDCA, any person that intends to import prescription drugs into the United States must ensure, among other things, that it only imports FDA-approved drugs that comply with their FDA approvals in all respects, including manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. 21 C.F.R. § 314.50. The importer must also ensure that each drug meets all applicable U.S. labeling requirements, and that such drugs are not imported in violation of the 'American goods returned' provision in 21 U.S.C. § 381(d)(1).33

FDA personnel do have some discretion regarding personal importation under certain circumstances, such as:

when the intended use is appropriately identified, such use is not for treatment of a serious condition, and the product is not known to represent a significant health risk; or when a) the intended use is unapproved and for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means; b) there is no known commercialization or promotion to persons residing in the U.S. by those involved in the distribution of the product at issue; c) the product is considered not to represent an unreasonable risk; and d) the individual seeking to import the product affirms in writing that it is for the patient's own use (generally not more than 3 month supply) and provides the name and address of the doctor licensed in the U.S. responsible for his or her treatment with the product, or provides evidence that the product is for the continuation of a treatment begun in a foreign country.34

However, this provision is expressly noted not to be a license for personal importation, generally.35

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35 See id.
B. Parallel Importation and Counterfeits in the United States

Though illegal, the downside of parallel importation experienced by the European Union, or the introduction of counterfeits in its legitimate drug supply, is occurring and growing in the United States. This situation exists because of the potential for re-importation via Internet pharmacy purchases through state government web sites and by individual citizens purchasing through web sites of their own choosing. The United States spends one billion dollars on Internet pharmacy purchases annually, and that number is rising.

In addressing parallel importation and Internet trade, much of the effort has focused on Canada due to its perceived safety and similarity to the United States. Although some web sites display Canadian or United States flags, they may not be located in these countries. There are the substantive questions as to the source of


these drugs: are they actually from the countries that the flags indicate, and are the drugs sold fake or tainted? Pfizer and Microsoft joined forces to prosecute international spam syndicates that attempted to sell counterfeit Viagra.\textsuperscript{38} CanadianPharmacy.com was one entity targeted by Pfizer and Microsoft, yet although an ostensibly Canadian site, the locations of individuals controlling this and related sites are unknown, while the drugs and purchasing supply chain spans the globe, including India, which is notorious for its fake drug supply.\textsuperscript{39}

The immense difficulty in finding international counterfeitors is virtually insurmountable if they are selling over the Internet. For example, a web address may be licensed in Russia; the server in China; the company payee for the credit card charge in the


\textsuperscript{39} See, e.g., John Leydon, Pfizer and MS Sue Viagra Spam gangs, THE REGISTER (U.K.), Feb. 10, 2005, http://www.theregister.co.uk/2005/02/10/spam_lawsuit. Canada has not been immune to imported counterfeits nor deaths associated with such drugs. Coroners, the Royal Canadian Mounted Police, and the Ontario College of Pharmacists are investigating several deaths associated with imported counterfeit cardiac drugs sold from a pharmacy there and, in addition, have brought charges against another pharmacist for selling fake drugs. See Coroner Probes Five Deaths in Pharmacy Investigation, CBC.CA, June 23, 2005, http://toronto.cbc.ca/regional/servlet/View?filename=topharmacy20050623; Luma Muhtadie, Fake-Drug Case: Huge Forensic Challenges, HAMILTON SPECTATOR (Canada), July 16, 2005, at A01 (deaths investigated associated with counterfeits raised to seven with forensic challenges). Note, however, that previous examples of counterfeit production have found counterfeit operations in Canada, targeting U.S. consumers. Naturtek, a Quebec site, was found to manufacture fake Viagra. See John Theriault, Testimony Before the Drug Imp. Task Force, Apr. 5, 2004, reprinted in http://www.hhs.gov/importtaskforce/session2/presentations/Pfizer.doc. However, counterfeiters in Europe, Canada, and Asia are expanding their counterfeit products to life saving medicines. It should also be noted that the volume of Internet imports is growing, and authorities such as Customs and Border Patrol in the United States simply cannot detect these entries due to limited resources. Both traditional U.S. international mail facilities as well as private carrier hubs for transport carriers such as FedEx, UPS, and others have been affected. See Statement of Jayson P. Ahern, Assistant Commissioner, Office of Field Operations, Bureau of Customs and Border Protection, Sales of Controlled Substances Over the Internet, Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, U.S. House of Representatives, Dec. 13, 2005, http://energycommerce.house.gov/108/Hearings/12132005hearing1738/Ahern.pdf. Beyond national efforts, private industry is attempting to educate law enforcement to spot counterfeits at the local level, including pharmaceuticals. See, e.g., Megan Burton & Kyle Almond, Counterfeit Goods Can Be Unsafe, NEWS 14 CHARLOTTE.COM (Dec. 6, 2005), www.news14charlotte.com/content/local_news/cabarrus/?AC=&ArID=108385&SecID=5.
United Kingdom; the processing of payment in Australia; and the product mailed from Chicago, using a return address of an unsuspecting customer of the website. The ease by which Internet pharmacies can procure drugs from outside the United States and then sell the fake, tainted, or questionable drugs within the United States is striking. Mark Kolowich, who personally admits to making "much more" than the seven million dollar government estimate selling counterfeit drugs before being caught, outlined the virtually effortless manner in which fake or tainted drugs from Mexico could be smuggled into the United States and sold via the Internet to U.S. and European customers.

Even companies registered in Canada may use imported and re-imported materials from other, less reliable countries for sale in the United States. For example, CanadaRx.net, a Hamilton, Ontario, registered company, has and does send drugs from its warehouse in the Bahamas; Canadatrust.com, a British Columbia

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registered company, was selling drugs re-imported from Mexico that were not approved by Health Canada or the FDA.\(^\text{43}\) In fact, most “Canadian” Internet pharmacies are anything but Canadian.\(^\text{44}\) Graham Satchwell, an international counterfeits expert, has commented on these developments, noting:

Advertisements were placed on the Web purporting to come from Canada and yet when drugs were ordered they frequently came from Malaysia, Vanuatu or Eastern Europe. Rates of counterfeiting in such places are high, but that aside, the


Note that the FDA, under its Operation Bait & Switch, has found that most drugs promoted as “Canadian” are really from many other countries, and many of these products were found to be counterfeit. Assessing drugs over several days in August 2005, the FDA assessed all mail packages from India, Israel, Costa Rica, and Vanuatu at JFK Airport, Miami International Airport, and Los Angeles International Airport, the FDA found that approximately eighty-five percent of the drugs they intercepted which were purportedly “Canadian” were from twenty-seven countries worldwide. More than forty percent of the orders had been placed with “Canadian” Internet pharmacies; yet only fifteen percent of the “Canadian” drugs found in this examination were actually from Canada. More than thirty products tested were found to be counterfeit. \textit{See FDA, FDA Operation Reveals Many Drugs Promoted as “Canadian” Products Really Originate from Other Countries, FDA NEWS, Dec. 16, 2005, http://www.fda.gov/bbs/topics/NEWS/2005/NEW01277.html.}

\(^{43}\) \textit{See Mary D. Shepherd, Drug Importation and the Vulnerability of Our Pharmaceutical Supply Chain, IMPROVING PATIENT CARE AND MEDICATION SAFETY, PROCEEDINGS OF THE NINTH ANNUAL ASHP MANAGEMENT CONFERENCE FOR LEADERS IN HEALTH-SYSTEM PHARMACY, Chicago, IL 10 (Oct. 2004). Note that even when caught and ordered to stop illegal importation, Internet importers using the Canadian marketing veneer continue to operate. For example, an Internet seller affiliated with RxDepot, which was ordered to stop illegally importing unapproved medicines, terminated its relationship with RxDepot and continued to sell unapproved drugs as the company “Canada Care.” See FDA Takes Action Against Company for Illegal Importation of Unapproved, Potentially Unsafe Drugs, FDA.gov, Dec. 1, 2005, http://www.fda.gov/bbs/topics/news/2004/NEW01142.html.}

\(^{44}\) A study performed by Cyveillance for the FDA found that of 11,000 sites it found claiming to be Canadian pharmacy websites, only 1,009 actually sold prescription drug products, and of those, only 214 were registered to a Canadian entity. \textit{See Jeff Clabaugh, Survey Finds Few Online Pharmacies Sell Drugs, WASH. BUS. J., June 13, 2005, http://www.bizjournals.com/washington/stories/2005/06/13/daily3.html.} Cyveillance notes that online brand abuses are seen “a lot” in the pharmaceutical industry. The balance of 795 pharmacy sites had registration information indicating a U.S. owner (the majority) as well as owners in Vietnam, the Czech Republic, and Barbados. \textit{See Ricardo Alonso-Zaldivar, FDA Casts Suspicion on Online Pharmacies, SEATTLE TIMES, June 15, 2005, http://seattletimes.nwsource.com/html/nationworld/2002336462_fda15.html.}
likelihood of drugs being time-expired or incorrectly stored are extremely high.  

C. Legal Vacuums and Disclaimers

Under this regime, parallel importation creates public health risks. Further, health regulations and government disclaimers result in little if any protection. It should be noted and emphasized that there is a legal loophole in health and safety regulation: drug shipments through countries like Canada or from Europe that are not for consumption by their citizens are not subject to those countries’ health safety laws. Using countries such as Canada or

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45 Top European Security Expert Warns Senate Panel on Risks of Drug Importation; Urges Congress to Learn from Problems Faced by European Union, PHARMALIVE, Apr. 19, 2005, http://www.forrelease.com/D20050419/dctu046.P2.04192005122047.06226.html (quoting Graham Satchwell, former detective superintendent and Association of Chief of Police Officers’ spokesperson on counterfeiting). Note that the product is not the only thing counterfeited. Randall W. Lutter, Acting Associate Commissioner for Policy and Planning at the FDA has indicated that not only are counterfeit drugs rife around the world, detection is difficult because the product packaging and labeling as well as containers are easily purchased, created, and/or counterfeited themselves. Hence, “well-organized criminals have the ability to exploit our regulatory system and profit at the expense of the public health.” See Randall W. Lutter, PhD, Counterfeit Drugs within the United States, Statement Before the Subcommittee on Criminal Justice, Drug Policy, and Human Resources, Committee on Government Reform, U.S. House of Representatives, (Nov. 1, 2005), reprinted in http://reform.house.gov/uploadedfiles/randall%20lutter%20testimony.pdf.

the United Kingdom as a "post office box" for imported and exported drugs avoids regulatory oversight of the safety and efficacy of these materials.

Further, state governmental re-importation programs provide no protection for products purchased through their programs. Government drug importation web sites disclaim liability for medicines purchased from those sites. For example, Washington state’s Canadian drug purchasing website indicates:

The state of Washington makes no warranty, express or implied, of merchantability and fitness for a particular purpose, and accepts no legal liability, with respect to any product offered, or pharmaceutical care provided, by the pharmacies listed on this Web site. Nor does the state of Washington make any representation regarding the legality or illegality of importing prescription medications from another country into the United States. The state of Washington will not indemnify or defend a user of this web site from federal, state, local or other prosecution, civil, criminal or administrative action.  

The State of Minnesota’s Rx Connect indicates:

Disclaimer of liability

The state of Minnesota makes no warranty, express or implied, of merchantability and fitness for a particular purpose, and accepts no legal liability, with respect to any product offered, or pharmaceutical care provided, by the pharmacies listed on this website.

The State of Illinois’s enrollment form indicates:

[T]he State of Illinois cannot guarantee the safety of any particular prescription drug purchase. The State of Illinois makes no representations or warranties as to the safety or efficacy of prescription drugs purchased from foreign sources.

Hence, there is virtually no formal, organized regulatory


48 See Minnesota RxConnect, Legal Information, http://www.state.mn.us/cgi-bin/portal/mn/jsp/content.do?programid=536902438&agency=Rx.

authority or legal recourse for consumers that ensures the safety and efficacy of parallel imported drugs or any remedy if harm results from their purchase.

As a practical matter, legal systems have for the most part been stymied in their efforts to hold Internet portals for medicines accountable for their product. Consumers in the United States and around the world, including the European Union, have been cheated and harmed by rogue Internet pharmacies with no remedy against these offshore facilities. William Hubbard, Associate Commissioner for Policy and Planning at the FDA, laments that the "FDA has no ability to take effective action against these foreign operators on behalf of U.S. citizens."

Secretary of the Department of Health and Human Services Michael O. Leavitt has described the situation:

You could go onto our Internet service provider, go to your search engine and put in 'Canadian drugs,' it would pull up a number of different sites. You will see one, I saw one the other day called the Canadian Generics. And it offered name brand drugs and generic drugs. FDA tracked it down to look at it; they found out that the Internet service provider was in China. They found that the Web site was managed out of Belize. They found that the check we sent them to buy drugs was cashed in St.

50 "The sale of drugs to U.S. residents via foreign websites is an extremely challenging area... Foreign sales pose the most difficult challenge for U.S. law enforcement because the seller is not within U.S. boundaries. Although the FDA may have jurisdiction over a resident in a foreign country who sells in violation of the [Food, Drug and Cosmetic Act] to a U.S. resident, from a practical standpoint, the Agency working with DOJ has a difficult time enforcing the law against foreign sellers, when they are hard to reach and outside our borders." Hearing on Internet Drug Sales Before the H. Comm. on Government Reform, 108th Cong. (2004) (statement of William K. Hubbard, Associate Commissioner for Policy and Planning, FDA), http://www.fda.gov/ola/2004/Internetdrugs0318.html.

51 Jim Thomson, CEO of the Centre for Mental Health in the United Kingdom, stated that, "[p]otent substances are freely available on the Internet and can be ordered easily without any prescription and any authentication of sources, making the public vulnerable to health hazards and public health vulnerable to growing antimicrobial and drug resistance." Global Forum on Pharmaceutical AntiCounterfeiting Calls for Increased Corporate Responsibility and a Framework Convention, EMEDIA WIRE, Mar. 21, 2005, http://pdfserver.emediawire.com/pdf/download/219649/pr.pdf.

52 Hearing on Internet Drug Sales, supra note 50.

Croix. And the postmark was in Dallas. We got the drugs, and the first box I looked at was impeccably counterfeited. It looked exactly like one that would come from a manufacturer. But when you tested the fluid that was in the syringe that it packaged, it was tap water. When you tested the chemical compound that made up the medications, it has the right ingredients, but they were just in the wrong proportion. Some of them were as high as 200 percent of what was supposed to be there. Some of them were as little as 50 percent. . . . I think drug safety is going to become a much bigger problem.

Parallel importation of drugs is illegal but happening in billion dollar proportions over the Internet; ironically, recent analyses have shown that such parallel trade may not in most instances be cheaper than U.S. purchases. Accountability for these sales is nonexistent, and, practically speaking, even in the context of laws aimed at attempting some formulation of liability for wrongdoing, perpetrators easily escape responsibility for their actions. The potential and actual financial and human harm is astronomical.

54 Letter from John D. Dingell, Ranking Member, Committee on Energy and Commerce and Bart Stupak, Ranking Member, Subcommittee on Oversight and Investigations, U.S. House of Representatives, Committee on Energy and Commerce to The Honorable Michael O. Leavitt, Secretary, Department of Health and Human Services (July 20, 2005) http://www.house.gov/commerce_democrats/Press_109/1091tr29.pdf.


Yet an AARP study showed that in the context of Medicare Part D medicine coverage, five of six common very common drugs were cheaper in the United States as compared to Canada. See Missouri Pharmacists Applaud AARP Shift in Drug Importation: Investigation Shows Greater Savings with Medicare Drug Benefit, PRNEWswire, Jan. 11, 2006, http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=104&STORY=/www/story/01-11-2006/0004247375&EDATE (discussing AARP study and Missouri Pharmacy Association comments upon it).
IV. Driving Forces for Counterfeits in Parallel Trade

A. Easy Profits

Money drives much activity around the world, and, unsurprisingly, it is a force driving the production and sale of counterfeits through parallel trade. The World Health Organization (WHO) and the FDA indicate worldwide sales of counterfeit drugs represent between $32 billion and $35 billion annually.\(^5\) Such figures represent $88-$96 million in illicit sales every day.

The sale of fake drugs through vulnerable trade paths is facilitated by the ease of counterfeit drug production. Compare making illicit drugs with licit counterfeits. Illicit drug production is a very difficult, expensive, and highly risky activity; producing heroin and cocaine surreptitiously is dangerous, requires great security and skill, and must produce a finished, viable, working product with clinical effects. Producing counterfeit licit drugs, on the other hand, is cheap, lucrative, and low risk. Manufacturing such products can employ unskilled workers, and need only result in materials that appear authentic—there is no burden on the producer that they actually result in any therapeutic functionality. Profit margins are dizzying. A fake pill may cost less than $0.01 to make, but can be sold for $0.30;\(^5\) and, in a coup de grace to marketing, such pricing still represents a discount compared with the actual drug. Besides this, selling licit drugs has none of the costs and risks of clandestine sales of heroin or cocaine.

B. Criminal Element

Because of high-level profits, concomitantly a high-level of organized crime is involved in taking advantage of supply chain weaknesses through importation and parallel trade. According to the FDA and international governmental authorities, counterfeit drug sales are linked to funding well-organized international criminal operations and terrorist activities, such as Hezbollah and Al Qaeda.\(^5\) These activities are also occurring in countries such

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\(^{56}\) Id. See also Cockburn et al., supra note 10, at 302.

\(^{57}\) Kerry Capell & Suzanne Timmons, What's in that Pill? In Latin America, Fake Drugs Are as Lucrative as Cocaine, BUS. WEEK, June 18, 2001, at 60.

\(^{58}\) See, e.g., Global Options Inc., An Analysis of Terrorist Threats to the American
as North Korea, which may engage in large-scale international crime sponsorship.\(^5^9\) It should also be noted that the FDA has identified the U.S. drug supply as a potential target for terrorists.\(^6^0\)


C. Light Penalties

Penalties around the world for counterfeit production are uniformly light. In Latin American countries, known for their cocaine and heroin production, governments have passed increasingly stringent laws to penalize and deter the manufacture and sale of cocaine. Thus, drug lords caught engaging in such activities may be incarcerated for ten to fifteen years in Latin American prisons.61

Yet laws regulating production of fake, licit drugs have not been strengthened accordingly with respect to the gravity of the harm. Penalties are light—often less than six months in jail, and with bail, perpetrators get out in just a few days.62 Therefore, an unintended consequence of penalties for illicit drug production is that sound business decision-making has led to a cheaper, less risky, and more lucrative product and market focus: counterfeit drugs. Hence, Latin America has become a source of counterfeit drugs while also being subject to this exploitation itself.63

Domestically, U.S. penalties for drug counterfeiting are also weak. Indeed, even the FDA recognizes this concern; counterfeiting a trademark may result in a decade in jail, but counterfeiting a drug may only lead to a maximum of three years in prison.64 In many cases drug counterfeiting may result in no jail

61 Capell & Timmons, supra note 57.
62 Id.
63 For example, estimates are that fifteen to twenty percent of the drugs sold in Peru are fake, stolen, or have expired. See Encarna Nu ez Diaz, Minsa Reports that 20% of Medicines Sold in Peru Are Counterfeit, WORLD MARKETS ANALYSIS, Apr. 14, 2005. LEXIS, News Library. Indeed, because of its limited enforcement budget, thirty percent of the 6,000 pharmacies in Lima, the capital, are unlicensed. Compounding the problem is that twenty percent of drug sales occur in the “informal sector,” id., such as night markets and other non-standard, non-pharmacy locations. The notorious “triple frontier” area between Argentina, Brazil, and Paraguay is infamous for its counterfeiting activities in medications and other products. Id. See Martin Krause, A New Balance on Counterfeit Goods, TECH CENTRAL STATION, Aug. 22, 2005, http://www.techcentralstation.com/082105SC.html.
These weak penalties prompt drug counterfeiting, as is the case in Latin America and the European Union.66 This combination has resulted in shifting illicit business practices. Convicted cocaine traffickers have entered U.S. markets selling not high margin, high-risk cocaine, but counterfeit drugs. For example, Domingo Gonzalez and Julio Cruz led a multi-million dollar counterfeit drug importation business. These convicted cocaine traffickers moved into fake drug sales and sold at least four million cholesterol medicine tablets and generated more than $10 million in sales before they were caught.67 As shown in headlines such as “Former convicts try a safer venture: Pharmaceuticals,” it is easy to shift into the counterfeit medicines trade.68

Other areas of the world suffer similar problems due to light penalties that encourage exploitation of parallel trade loopholes to introduce counterfeits. In the European Union, like the United States and Latin America, penalties are light. For example, Allen Valentine, the mastermind behind the U.K. counterfeit production scheme that was producing and selling counterfeit products across Europe,69 had been convicted on fourteen previous occasions for medication fraud; yet he only received a sentence of five and a half years—and the sentence was due to his infringement of intellectual property rights, rather than any threat to public health.70 More outrageously, it is possible that he will be released


66 As well as the United Kingdom and Asia. See infra notes 76-78 and accompanying text.


69 See Lister, supra note 19 and accompanying text.

70 Id.
in less than half that time; he is eligible for release in two years.71 The Valentine case follows several recalls and U.K. counterfeit discoveries72 with similar light penalties for perpetrators, some including no prison time at all.73

Asia is not immune to the light penalties in counterfeiting drugs. Taiwan assessed the number of counterfeiting cases brought to public prosecution and their attendant penalties. From 2003 to 2004, 137 cases of counterfeit drug importation and sale were tried in Taiwan. Of all those cases, eighty-two resulted in sentences of less than six months, and only one resulted in a penalty of greater than two years.74

Around the world, domestic and international policy makers fail to take counterfeit drug production seriously. It is no wonder that trade in counterfeit drugs is burgeoning; low risk, low penalties, and high profits create tempting opportunities for the amoral businessperson.

D. Difficult Detection

Another facet driving the counterfeit drug trade is the limited ability to detect the fake product. Trading counterfeit drugs may be the perfect crime.75 Physicians and nurses generally fail to

71 Id.
72 Satchwell, supra note 20. Counterfeit Cialis and Reductil were detected in August and September 2004. See MATTHEWS, supra note 20.
73 An individual found guilty of selling counterfeit Viagra worth £440,000 in the United Kingdom was sentenced to 150 hours of community service and £1,250 in fines by Isleworth Crown Court. See Bridget Carter, Man Caught Selling Fake Viagra Escapes Jail Term, THE SCOTSMAN, June 24, 2005, http://news.scotsman.com/latest.cfm?id=4738210.
74 Li-Ling Liu, Deputy Dir. Gen., Bureau of Pharmaceutical Affairs, Taiwan Dep’t of Health, Current Status of Anti-Counterfeiting in Chinese Taipei, Address at the 2005 Symposium of APEC Network: Pharmaceutical Regulatory Science (Nov. 14, 2005). It should also be noted that in Taiwan, sentences can often be exchanged for payments to the government in lieu of incarceration, resulting in no prison time required. Personal communication with Oliver Yoa-Pu Hu, Ph.D., Dean of Research & Dev., Nat’l Def. Med. Ctr., in Taipei, Taiwan (Nov. 14, 2005).
75 See Joel B. Finkelstein, Drug Reimportation Situation is Shifting as Canada Could Cut Availability, Rx4US, Jan. 24, 2005, http://rx4us.com/en/prescription+drugs+news/drug+reimportation+situation+is+shifting+as+canada+could+cut+availability.html. Note that counterfeiters have entered the medical device market, including fake surgical supplies. See Medical Device Importer to Pay $10K Fine, SOUTH FLORIDA BUSINESS JOURNAL, July 18, 2005,
consider that therapeutic failure could be attributable to a fake drug, instead ascribing poor patient outcomes to human variation. Similarly, providers, patients, and families may be unaware that they were victimized by a fake medicine, analogous to patients dying without knowledge that their illness was in fact treatable. The patient’s status may also limit any suspicion of the presence of a fake drug; he or she may be frail, elderly, and/or very ill, creating a tendency to believe the therapeutic failure or death was associated with these characteristics rather than treatment.

Detection is also limited by the lack of provider insight into the source of drugs. Providers infrequently ask where the patient purchased their medications; further, even in the rare event that they do, patients may not wish to disclose to their providers that medicines were purchased on the Internet or from a foreign


A tragic case from China illustrates medical professionals’ failure to consider the existence of fake drugs. A six year old girl died after receiving a fake Hepatitis A vaccine; physicians repeatedly assured the father that his daughter was fine even though she exhibited clinically worsening signs, turned purple and blue, and foamed at the nose and mouth. See Father Was Told Dying Daughter Was Fine After Illegal Vaccination, RADIO FREE ASIA, July 22, 2005, http://www.rfa.org/english/news/social/2005/06/29/china_vaccinations/.

For example, in one counterfeit case, only about ten percent of the fake drug was ever recovered. Hence, nearly ninety percent of the counterfeit drug may have gone undetected and been injected into 25,000 cancer and HIV patients. See Gilbert M. Gaul & Mary Pat Flaherty, Lax System Allows Criminals to Invade the Supply Chain, WASHINGTON POST, Oct. 22, 2003, http://www.washingtonpost.com/ac2/wp-dyn/A61473-2003Oct21?language=printer. In some cases, the physician or nurse may assume the patient is not being truthful when asked whether he or she is taking the drug appropriately, and attribute therapeutic failure to patient noncompliance. In addition, some fake drugs are made for asymptomatic clinical conditions such as high cholesterol or hypertension, so any therapeutic effect or lack of thereof is not obvious. The placebo effect may also result in clinical action, even though there is no active ingredient in the drug. See Marv Shepard, Drug Equality, Safety Issues and Threats of Importation, 36 CALIF. W. INT’L L.J. 77 (2005).

country. 79

Other practical factors in the medication process contribute to challenges in detecting counterfeit drugs. The medication packaging is thrown away, making any investigation on that basis unworkable. The suspect drug is metabolized by the patient’s body once taken, limiting the ability to detect the fake drug ingested. Further, there are few laboratory screening tests available to detect the thousands of drugs that patients could be taking and drug levels are not easily obtained. 80

There is little suspicion or discussion about counterfeits, and evidence that might point to their presence is discarded or digested. 81 This situation creates a forensic quandary in efforts to determine the presence and circumstances surrounding a potential fake medicine; such difficulties are blocking effective investigations in Canada associated with counterfeit drug deaths

79 This situation may be due to embarrassment or stigma associated with a particular disease state or frustration with access to the care desired. See Jim Thompson, Stigma? What Stigma?, EHI PRIMARY CARE, Sept. 6, 2005, http://www.ehiprimarycare.com/comment_and_analysis/index.cfm?ID=100.

80 Note also that if the drug is a suspected fake, determination of its authenticity is difficult. Drug tests for the legitimate drug may not be available; if they are, one has to know what fake material to test for—a daunting task with the tremendously diverse array of substances used to create counterfeit drugs.

81 Even well-known cases where information and the fake materials are available for analysis present challenges to any investigation and prosecution. Governments may also attempt to suppress information about counterfeits, through measures such as false certification of the drugs, creating significant barriers to detection. See Cockburn et al., supra note 10, at 1-2. Industry, because of fears that legitimate drug sales would be adversely affected, may not provide broad information about detection and scope of counterfeits. Id. at 2. Further, physicians and government officials may be part of the illegal activity. See 12 Doctors Involved in Spreading of Fake Drugs, SUN STAR, Aug. 21, 2005, http://www.sunstar.com.ph/static/pan/2005/08/31/news/12.doctors.involved.in.spreading.of.fake.drugs.health.office.html.

there.  

It should also be noted that detection is difficult because of the quality of the packaging and counterfeit product itself. Counterfeiters often have highly developed tools, and the fake creation appears identical to the actual medicine in both its packaging and the substantive product itself. A former detective superintendent and former Association of Chief Police Officers' spokesperson on counterfeiting, in testimony for the Senate Health, Education, Labor, and Pensions committee, noted that:

counterfeit medicines often appear so like the genuine product that no one, not the best specialist can tell the genuine packaging from the counterfeit. And no one, not the best specialist can tell the genuine product from the counterfeit unless the product is subjected to chemical analysis. The result is that everyone, poor, ignorant, rich and smart, all are at risk from counterfeit or sub-standard products—and they probably won’t recognize them when they see them.

In the course of my work I have myself negotiated to buy counterfeit medicines from China, Germany, Poland, India, Pakistan and other countries. It is extremely easy for anyone to find a foreign party willing to counterfeit medicines (without active ingredients) and present those medicines in packaging that will easily pass as genuine.

Hence, the limited suspicion and detection ability, even by experts in the field, provides fertile ground for those who would manufacture and sell counterfeit medicines to an ignorant public.

V. The Pharmaceutical Market Access and Drug Safety Act

Congressional efforts have been made to allow parallel importation into the United States. The major drug importation bill from the 109th Congress is the Pharmaceutical Market Access

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82 See Luma Muhtadie, Fake-drug Case: Huge Forensic Challenges, HAMILTON SPECTATOR, July 16, 2005, at A01 (describing investigations into seven deaths associated with suspected counterfeit drugs, which “[are] definitely going to be a major forensic challenge”).

and Drug Safety Act of 2005, introduced by Senator Byron Dorgan.\textsuperscript{84} This bill proposed to amend the Food, Drug, and Cosmetic Act\textsuperscript{85} to permit both commercial and personal importation of prescription drugs.

A. General

Under the bill, the Secretary of the Department of Health and Human Services would promulgate regulations allowing importation through registered exporters and registered importers from a potentially expanding number of countries. Personal importation of drugs would be permissible while regulations regarding a commercial importation system are written. In an effort to prevent drug manufacturers from penalizing or limiting sales to foreign suppliers participating in the commercial importation program,\textsuperscript{86} federal precedent currently holding that foreign sale of a product does not exhaust the domestic patent and intellectual property protections would be overruled.\textsuperscript{87}

\textsuperscript{84} S. 334, 109th Cong. (2005), http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_bills&docid=f:s334is.txt.pdf. Co-sponsors included Sens. Snowe, Grassley, Kennedy, McCain, Stabenow, Chafee, Jeffords, Lott, Dayton, Clinton, Bingaman, Boxer, Conrad, Durbin, Feingold, Feinstein, Inouye, Johnson, Kohl, Leahy, Levin, Nelson of Florida, Obama, Pryor, Salazar, Sarbanes, Schumer, and Collins. The Dorgan bill has bipartisan support and the most co-sponsors, making it the leading legislative vehicle. Note that there have actually been federal laws allowing importation. In 2000, the Medicine Equity and Drug Safety Act, 21 U.S.C. §284 (2000) was passed, which would allow drug importation in the effort to reduce medication prices. However, then-Secretary of the Department of Health and Human Services, Donna Shalala, de- implemented the statute. Under §384(l)(1), Secretary Shalala was empowered to do so if she could not certify that implementation of bill would “pose no additional risk to the public’s health and safety.” \textit{Id.} Due to the inability of the Secretary to do so, the bill’s importation provision was decertified. In addition, the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2087 (2003), superceded the Medicine Equity and Drug Safety Act, and allowed for importation from Canada, again only if the Secretary could certify no additional risk to the public’s health and safety. No such certification has been made. \textit{Id.}


\textsuperscript{85} 21 U.S.C. §§381-804.


\textsuperscript{87} See Jazz Photo Corp. v. Int'l Trade Comm., 264 F.3d 1094 (Fed. Cir. 2001), \textit{cert.}
B. Safety Issues: Permitted Countries

The bill’s provisions raise significant safety concerns that stem from other parallel importation experiences. Personal and commercial importation would be allowed from Canada, Japan, Australia, New Zealand, Switzerland, as well as other countries in the European Union. Yet many of these countries are subject to and suffer from counterfeit problems themselves, particularly the European Union. Other countries may be added to the list of


Members of the Senate Health, Education, Labor, and Pensions Committee also had safety concerns within the bill. Sen. Gregg, former Committee chairman, “challenged [Sens. Dorgan, Stabenow, Snowe, and Vitter] on their legislation, saying it would make too many changes to existing food and drug law.” Kate Schuler, Drug Reimportation Hearing Allows Sen. Enzi to Drop Hints on Possible Legislation, CQ TODAY, Apr. 19, 2005, at 12. “In a heated exchange with Snowe, Gregg pressed the issue of safety and grilled her on the changes that the bill would make to the current FDA inspection and approval system. ‘We have a system that works,’ Gregg said. ‘To stop into this area requires that we do it correctly, and I have serious reservations’ about the bill.” Id. at 12. Other experts were concerned about its provisions. According to Graham Satchwell, a noted expert on pharmaceutical fraud in Europe, the bill would “not afford your citizens the protections they currently enjoy. As it stands, S.334 does not afford confidence that a drug from a ‘permitted country’ will have originated there or have been subject to appropriate regulation.” Top European Security Expert Warns Senate Panel, supra note 22.

See S. 334, supra note 84, at 9-10.

See supra notes 18-28 and accompanying text (discussing EU problems with counterfeit drugs). Countries that would immediately be allowed to provide imported drugs under the bill’s provisions would include Austria, Belgium, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Luxembourg, The Netherlands, Portugal, Spain, Sweden, and the United Kingdom. Some of these countries have encountered significant problems with counterfeits. See id. Indeed, testimony by John Theriault, Vice President for Global Security, Pfizer, Inc., before the Drug Importation Task Force noted that:

“[w]ith the exception of Italy and Luxembourg, counterfeit Pfizer products were found in each of the EU member countries, as well as in eight of the fifteen candidate countries (Bulgaria, Estonia, Hungary, Malta, Poland, Romania, Slovakia, and Turkey). Austria, Australia, Israel, Japan, New Zealand, Norway, Switzerland and South Africa are also among the countries where counterfeit Pfizer products were detected. Seizures in the Asia-Pacific region included counterfeit packaging not for the local markets, but for those in the U.S. and Australia.”
permitted traders if those countries have laws on the books that include a review of drug safety and efficacy, good manufacturing processes, adverse event alert mechanisms, and labeling and promotion rules. Unfortunately, countries may fulfill these requirements in form but not implement them in substance.

C. Inadequate Resources

It should be noted that, beyond other countries' difficulties in enforcing safety standards, the FDA in the United States has been criticized for inadequate safety and public health activities. This includes the Vioxx withdrawal, which was initiated by Merck, the manufacturer, and not ordered by the FDA; problems associated with antidepressant use in children; as well as counterfeit drugs.

A root cause of this problem is that the FDA is chronically underfunded. Unfortunately, this circumstance leads to good faith FDA personnel having to make uncomfortable choices as to which safety policies to enforce. This reality indicates that the U.S.


91 See S.334, supra note 84, at 10-11.

92 For example, Russia is a country that fulfills this provision, as may China and India—countries that have legitimate pharmaceutical industries, but are well known for their counterfeit drug production. See, e.g., Moscow Police Bust Counterfeit Medicine Factory, MOSCOW NEWS, July 12, 2005, http://www.mosnews.com/news/2005/07/12/falsedrugs.shtml (describing Moscow police bust of counterfeit medications which were sold in Moscow, St. Petersburg, and other regions).


94 See infra note 162 and accompanying text (noting the FDA released counterfeit Sidenafil (Viagra)).

95 See, e.g., Charles Marwick, FDA Funding Problems Imperil Safety of Biological Products in the United States, 279 J. AM. MED. ASS’N 899 (1998); Arthur A. Levin, The FDA, Politics, and Public Protection, CENTER FOR MEDICAL CONSUMERS, (Nov. & Dec. 2002), http://www.medicalconsumers.org/pages/science_under_attack.html (“User fees also have provided Congress with cover for their historic under-funding of the FDA. The result is that the agency cannot adequately carry out many of the public protection duties that Congress has assigned it.”); Mark D. Uehling, A New Drug Safety Database for Pharma, FDA, ITWORLD.COM, May 17, 2005, http://enterprisesecurity.symantec.com/industry/healthcare/article.cfm?articleid=5713&EID=0 (“Congress chronically underfund[s] the FDA’s MedWatch drug safety program”).
drug safety system has significant resource challenges to monitoring domestic drug safety. This makes it highly unlikely that the FDA could incur greater responsibilities for the security and safety of pharmaceuticals where it would have to monitor domestic supplies as well as inspect and monitor other countries’ systems that may be, in practice, only existent on paper and not in reality.

Limited regulatory resources would also impact the mandates for registration requirements for importers and exporters under the proposed legislation. Under the bill, importers and exporters are required to register with the Department of Health and Human Services.\(^{96}\) Registration requirements are extensive, and include place of business, warehouse locations, and locations of other related facilities.\(^{97}\) In addition, the bill mandates that information regarding the source of imported drugs, as well as a promise that the registrant will not import or export drugs that do not qualify under the bill, are also to be documented by the Department of Health and Human Services for each importer or exporter.\(^{98}\) The Secretary must act within ninety days to approve or deny the registration application.\(^{99}\)

Such administrative requirements seem onerous for the FDA given its current resources as well as its expanded safety mandates and responsibilities under the bill. Indeed, verifying all registrant information domestically as well as internationally, sources of proposed drugs for export/import, and other critical characteristics of the exporters and importers under a ninety day time constraint is virtually impossible. As such, important components of the safety structure would not be attended to, and would likely be within the set of mandates unfulfilled and unenforced by the FDA.

### D. Pedigree Limitations

To ensure the safety of parallel imported drugs, the bill requires that the drugs be accompanied by a paper pedigree statement indicating their chain of custody.\(^{100}\) Yet when one notes

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97 See id.
98 See id. at 13-14.
99 See id. at 18.
100 "(3) The exporter or importer obtained the drug—(B) directly from an entity
drug counterfeiters' talents in creating realistic holograms, package inserts, and the drugs themselves, creating reasonable fake pedigree documentation would not appear to be an effective deterrent. Further, due to limited resources and because inspection and verification require significant time, energy, and expertise, checking pedigree papers may not be an administrative priority.

In addition, the bill relies on contractual agreements between parallel trading partners to police validity of papers, not criminal law. Hence, to keep traders honest, the bill contemplates breach of contract actions to ensure pedigree accountability. Unfortunately, in the world of counterfeit drugs, there is a criminal element that must be considered. A potential civil suit by legitimate business entities would provide no incentive for the manufacturer and seller of fake drugs to change its behavior, assuming it is ever caught.

It should be noted that there are provisions within the bill that require foreign exporters to subject themselves to inspections, including determination of pedigree. The Secretary of the Department of Health and Human Services may assign one or more employees to this inspection; under the bill, these inspections must be performed by the FDA at least twelve times annually. The practicality of these pedigree inspections is limited by resources. It is difficult to see how all these facilities will be inspected at least once a month; recall that facilities that can range

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101 See Robb Miller, Tracking Papers Won't Help, USA TODAY, May 31, 2005, at A12 (indicating pedigree papers are easily forged, would impose high costs, and may result paradoxically in a false sense of security since they can be used to "wash" products to make them appear legitimate).

102 See S.334, supra note 84, at 24.

103 See id. at 25. The duty of the Secretary of Department of Health and Human Services is to inspect and verify chain of custody. Id. at 31.

104 See id. at 26.

105 The FDA would be responsible for these activities, since it would receive fees from registrants participating in the program. See id. at 36, 41.

106 See id. at 27.
from Australia to Japan to Latvia. More inspectors would necessarily need to be hired to fulfill this provision of the bill alone. The FDA has only 16.9 full-time equivalent inspectors for all of the international mail facilities in the United States.\(^\text{107}\) Current levels of resources and staffing would be completely inadequate to verify the quality and pedigree of the hundreds to thousands of exporters that would participate under the bill’s provisions.\(^\text{108}\)

**E. Pre-Import Information Collection**

The proposed legislation mandates that pre-importation notice be given to the relevant governmental agency “not less than eight hours and not more than five days in advance of the time of the importation of a shipment of qualifying drugs.”\(^\text{109}\) The information required under the proposed bill includes:

- the name and complete contact information of the person submitting the notice;
- the name and complete contact information of the importer involved;
- the identity of the drug, including the established name of the drug, the quantity of the drug, and the lot number assigned by the manufacturer;
- the identity of the manufacturer of the drug, including the identity of the establishment at which the drug was manufactured;
- the country from which the drug is shipped;
- the name and complete contact information for the shipper of the drug;
- anticipated arrival information, including the port of arrival and crossing location within that port, and the date and

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\(^{107}\) TASK FORCE, supra note 2 at 56, Figure 5.3. Note that inspecting imported medicines is not these employees' only duty.

\(^{108}\) Note that the number of inspections of registered exporters in the first year would be a minimum of 600 (twelve inspections a year with a minimum of fifty), see S.334, supra note 84, at 92, and for the second year, a minimum of 1,200 (twelve inspections a year with a minimum of 100); the number of importers would be even greater, with at least 1,200 the first year (twelve inspections a year with a minimum of 100), and at least 2,400 the second year (twelve inspections a year with a minimum of 200). See id. at 93-94.

\(^{109}\) See id. at 28-29.
time;
• a summary of the chain of custody of the drug from the establishment in which the drug was manufactured to the importer;
• a declaration as to whether the Secretary has ordered that importation of the drug from the permitted country cease under subsection (g)(2)(C) or (D); and
• such other information as the Secretary may require by regulation.110

This breadth of information would require a new infrastructure just to collect and collate the information; verification would require even more resources. Once again, limited resources may lead to a lack of enforcement, or the draining of scarce resources from direct safety-related efforts.

F. Funding

To pay for its provisions, the bill requires importers111 and exporters112 to pay a registration fee and an inspection fee. However, this arrangement represents financial underwriting of government scrutiny by those to be scrutinized, creating at least the appearance of a conflict of interest.

The bill's contemplated funding mechanism is similar to pharmaceutical drug application user fees paid to the FDA. Many sources have criticized this practice.113 Hence, for importers and exporters who fund their own review process, a similar appearance of impropriety arises. Such a system may subject the FDA to Congressional budget cuts and conflict of interest charges since it will be the primary beneficiary of these fees under the proposed

110 See id. at 29-30.
111 See id. at 32.
112 See id. at 37.
legislation. Therefore, this kind of approach, which has raised potential safety concerns in other pharmaceutical contexts, is inappropriate to ensure the safety of the medicine supply under a parallel importation regime.

G. Bioequivalence and Excipients

The bill would permit non-bioequivalent drug versions to be imported into the United States. Non-bioequivalent drug forms generally include different excipients; excipients are the non-therapeutic materials within the drug.

As a clinical matter, it is well-known that different excipients create risks of adverse drug reactions. In fact, the FDA has noted that excipients can be toxicants, with adverse reactions including renal failure, osmotic diarrhea, hypersensitivity reactions, cardiotoxicity, and death. Domestically in the United States, even drug forms deemed bioequivalent by the FDA have nevertheless resulted in adverse drug reactions.

If parallel trade is permitted as contemplated by the bill, the international definition of “bioequivalent” will be crucial to ensure the safety in medicine supplies. Unfortunately, international

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114 S.334, supra note 84, at 36. The Bureau of Customs and Border Protection would be an optional beneficiary of such fees. Id.

115 See Fontanarosa et al., supra note 113.

116 S.334, supra note 84, at 61-63.


120 See Mark D. Grebenau, URGENT: Reports of Substitution of NEORAL with Generic Equivalents of SANDIMMUNE, Novartis Dear Healthcare Provider Letter, http://www.novartis-transplant.com/medpro/drug_substitution.jsp (describing that one form of a transplant drug described by the FDA as therapeutically equivalent was in fact not equivalent to the other form).
definitions, including those used in the European Union and Latin America, are not harmonized.\footnote{Bioequivalent, or, as it is known in the European Union, “essentially similar” medicines, are often not defined within regions. See, e.g., Trevor Cook, Regulatory Data Collection of Medicinal Products in Europe, BIO-SCIENCE L. REV. (Mar. 6, 2003), http://pharmalicensing.com/features/disp/1046957520_3e674dd06906d (European definition of “essentially similar” is absent under EU directives, or is established by each independent regulatory authority); Núria Homedes, et al., Generic Drug Policies in Latin America, HEALTH, NUTRITION, AND POPULATION DISCUSSION PAPER, WORLD BANK (Mar. 2005), http://siteresources.worldbank.org/HEALTHNUTRITIONANDPOPULATION/Resources/281627-1095698140167/HomedesGenericDrugFinal.pdf (describing a survey study discovering that bioequivalence has different meanings across Latin American countries).} This situation will create significant conflicts and raise legal issues associated with imported purportedly bioequivalent versus non-bioequivalent drug imports.\footnote{This will include warning labeling. See S.334, supra note 84, at 61-63. Note also that individual importation would also be allowed if non-bioequivalent labeling is provided. See id. at 62. Yet this is a highly dangerous action; if excipients make the drug version a poor choice for the patient, the drug actually is a different formulation, or the patient discovers the non-bioequivalence and decides not to take the drug, significant negative therapeutic consequences can result.} More importantly, patient care is jeopardized. Hence, under the bill’s provisions, if two drugs are labeled bioequivalent when their excipients are not, the drugs are not bioequivalent and adverse reactions may occur. Investigating their causes may become an exceedingly complicated endeavor requiring significant time and resources and subjecting more patients to harm in the interim.

\[H. \textbf{Intellectual Property Changes}\]

The bill attempts to preempt efforts by pharmaceutical companies to act against entities wishing to participate in the parallel trade program.\footnote{\textit{See id.} at 73-74.} Under the bill’s provisions, pharmaceutical companies would be mandated to sell under the same conditions to all suppliers, regardless of whether the seller participates in the parallel trade of drugs into the United States. The bill also requires that all drugs be the same in form and in packaging; this provision is to prevent manufacturers from determining whether drugs were intended for distribution in the United States or a foreign country.\footnote{\textit{See id.} at 75.} Further, under the bill, resale of a drug sold for
or to a foreign entity which is then brought into the United States for parallel sale is not an act of patent infringement.\textsuperscript{125}

Such provisions are included in the bill to prevent gaming of U.S. intellectual property laws in an effort to stop the parallel importation program. Current federal law permits such suits.\textsuperscript{126} These proposed changes could potentially limit pharmaceutical company gaming, yet they may also prevent companies from protecting the public—and protecting the company from potential lawsuits—by refusing to sell to unreliable or criminal actors. Because many companies have their own investigative units, they may identify certain suspect business entities. Even if such entities are identified, so long as they are registrants under the parallel importation program, the proposed statute mandates that they cannot be discriminated against, and therefore they must be sold to under standard conditions. This situation may result in the risk of pecuniary and nonpecuniary harm to the pharmaceutical company as well as the patient if fakes are introduced through the parallel trade stream.

\textbf{I. Security}

The bill attempts to provide protections against patient harm through mandated security measures. The bill specifies that track and trace as well as other anti-counterfeiting technology must be established through regulation by the Secretary of the Department of Health and Human Services\textsuperscript{127} within ninety days from enactment of the statute.\textsuperscript{128}

However, drug safety technology is not currently advanced enough to ensure security of the drug supply. The FDA notes that radio-frequency identification (RFID), a primarily advocated system, as well as other technology, is at present undeveloped and will probably not be ready for implementation until at least 2007.\textsuperscript{129} Further, pilot testing of RFID found a twenty-seven

\textsuperscript{125} See id. at 89.

\textsuperscript{126} See Jazz Photo Corp. v. Int'l Trade Comm., 264 F.3d 1094 (Fed. Cir. 2001), cert. denied, 536 U.S. 950 (2002).

\textsuperscript{127} See S.334, supra note 84, at 108-09.

\textsuperscript{128} See id. at 110.

\textsuperscript{129} Of course, this only relates to initial use of the technology. FDA Announces New Initiative to Protect the U.S. Drug Supply Through the Use of Radiofrequency
percent failure rate.\textsuperscript{130} For large wholesalers with more than 1.39 million deliveries a day,\textsuperscript{131} this failure rate is unacceptable. It also shows that a ninety-day implementation window is unrealistic and untenable from government, patient, and private industry standpoints.

An industry spokesman indicated that, "RFID is great for tracking cardboard. But to get to actual medicine safety, much more needs to be done."\textsuperscript{132} Others in Congressional testimony have noted the significant drug security problems that focusing upon tracking packaging:

New anti-counterfeiting technologies have numerous shortcomings including the following:

\begin{itemize}
  \item In almost every case, the technology, be it a hologram, tamper proof labels, embossing, thermo-reactive ink, RFID tags, DNA markers, and the like, enable companies to track cardboard, not product. It is not unusual to find genuine product in counterfeit packaging and counterfeit product in genuine packaging.
  \item In the United States and in the European Union, the two largest pharmaceutical markets in the world, repackaging is legal; thus, without violation of any law, packaging, with all types of expensive, state of the art secure devices, can end up in the trash or worse, in the hands of a counterfeiter, while...\end{itemize}

\textsuperscript{130} Robert P. Giacalone, \textit{Drug Wholesaling and Importation: Challenges and Opportunities?} 1st Annual San Diego Health Policy Conference, June 3, 2005 (noting that Cardinal Health, one of the three major drug wholesalers distributors in the United States, found upon testing that only seventy-three percent of RFID tags were readable, and that broader testing found that wholesalers had failure rates of three and a half percent to twenty-one percent). The immaturity of RFID can be illustrated by a major event in the RFID track and trace pharmaceutical effort. This was a pilot project announced by a single drug manufacturer, a single wholesaler (not one of the “big three”), and a single technology company, for only one drug. \textit{See, e.g.}, \textit{SupplyScape and Unisys Pilot Pharmaceutical Industry’s First Electronic Pedigree System for Commercial Drugs}, \textit{Business Wire}, May 31, 2005, http://www.unisys.com/about_unisys/news_a_events/05318546.htm. It is conceivable that the costs associated with such projects will be exceedingly high, given capital costs that will be required to implement the program, including different wholesalers for different drug manufacturers, for different drugs.

\textsuperscript{131} Giacalone, \textit{supra} note 130.

\textsuperscript{132} \textit{Id.}
genuine product is legally distributed in packaging with no security features.

- RFID technology which was featured in a FDA task force report is more of an inventory management tool than an anti-counterfeiting device.

- A counterfeiter or diverter could purchase RFID tags and attempt to mimic manufacturers' RFID codes.

- Industries which have and are using RFID products have noted that when their products enter the 'grey market,' their RFID tags are often 'zapped' rendering them unreadable.

- Counterfeiters generally deal, not only with counterfeit product, but with diverted, expired, and stolen product as well. Envision the scenario where a counterfeiter steals product, removes genuine product from the 'secure packages', and then puts the counterfeit product in these packages, and then reinserts the counterfeit product back into the system. The counterfeit product would pass through all the readers successfully. What then happens to the genuine product? The irony is that the genuine product would most likely be repackaged in counterfeit packaging with unreadable tags and entered into the distribution system. If the RFID system works correctly, the genuine product would be kicked out of the system, but later determined to be genuine, undermining any confidence in the system.133

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Industry specialists note other implementation challenges. These include industry agreement on a rollout timetable, technology standards, RFID tag and reader
As a result of these significant drug safety problems, technological tools are being developed for drug supply security, but broader and robust application and reliability have not yet been established. Any reliance on technology as a panacea for ensuring safety and security of the drug supply is sorely misplaced.

J. Internet Regulation

The bill does attempt to regulate Internet pharmacies, but regulating the irregular and offshore nature of Internet businesses presents tremendous challenges, not the least of which is regulating the quality of drugs sold. Congress has repeatedly voiced its concerns regarding the situation:

For the past 15 years, the Committee on Energy and Commerce has been actively investigating a range of issues related to the sale and distribution of prescription drugs entering into the United States from foreign sources. As part of this effort, we have directed minority staff to visit various border crossings, international mail-branch facilities, and major consignment carriers to examine the types and amounts of unapproved prescription drugs entering the United States. In particular, these hearings have extensively examined the problem of rogue Internet pharmacies and how the drugs sold on these Web sites enter the U.S. through the U.S. international mail facilities and express consignment carriers, such as FedEx, UPS, and DHL.

Through these hearings and repeated correspondence, we have provided extensive input into how and why current policies availability, and agreements and ownership of data and on data sharing. See Kontnik, supra note 12. Further, countries such as Russia, with a large counterfeit problem, note that security systems will have little effect due to counterfeiter ability to mimic security systems as well. See, e.g., Fake Medications Inundate the Russian Pharmaceutical Market: The Russian Experience in Introducing Special Marks for Licensed Video and Audio Production Has Not Resulted in Any Positive Changes, PRAVDA, May 4, 2005, http://english.Pravda.ru/main/18/89/357/15406_medicine.html.

adopted by key agencies responsible for combating this problem—namely, the Drug Enforcement Administration (DEA), the Bureau of Customs and Border Protection (Customs), and the Food and Drug Administration (FDA)—are ineffective. . . . It remains clear to us that the unabated flow of unregulated drugs entering the U.S. poses a growing threat to the Nation’s public health. The nature of online pharmacies and the inability of key agencies to provide even rudimentary controls over rogue Internet pharmacies is producing measurable harm. For example, it is likely that at least some of the unregulated drug flow that we have documented entering the U.S. from foreign sources is finding its way into the wholesale chain, and even onto pharmacy shelves. . . .

Our investigation has repeatedly demonstrated the ease at which foreign-purchased prescription drugs can enter the U.S. with the click of a mouse, and anybody who has visited an international U.S. mail facility would understand that the Internet is the source of many of these drugs. . . .

The volume of [shipments of controlled substances] were overwhelming all efforts to adequately process or deny entry to the bulk of these drugs. While Customs and the FDA were making some attempts to stop a portion of these drugs (mostly the controlled substances), after the purposeful release of hundreds of packages of counterfeit Sidenafil [Viagra], it became evident through visits to other mail facilities that the entire screening system had collapsed. In short, the system used by Customs and FDA was no longer capable of addressing this problem.135

The bill’s provisions attempt to utilize the Federation of State Medical Boards’ National Clearinghouse on Internet Prescribing as the guardian of safety for Internet pharmacies. Yet, such reliance is misplaced; first, the Federation of State Medical Boards had no knowledge of its role; second, its clearinghouse is focused on monitoring unethical physician prescribing practices, not

identifying suspect Internet pharmacies.\textsuperscript{136}

**VI. Policy Efforts**

Any attempt at parallel trade in pharmaceuticals in the United States must be preceded by significant attention to a wide array of factors in order to ensure the safety of the pharmaceutical supply. An interdisciplinary public policy is essential to adequately ensure sound control of medicines entering the country now, before any potentially harmful parallel trade is allowed. At a minimum, a four-part strategy must be coordinated involving public health efforts, an integrated reporting system, penal reform, and investment in technology prior to the introduction of any broad-based parallel importation scheme into the United States.

**A. Public Health Campaign**

Any influx of counterfeit drugs, particularly through illicit parallel importation such as Internet sales, is a public health risk. As such, public health efforts must be part of the policy that protects citizens from harm associated with tainted or fake medicines.

Like other public health issues such as obesity and cigarette smoking, policy solutions must be interdisciplinary and aggressive.\textsuperscript{137} For potential counterfeit drugs, the first step is to raise awareness among patients. A public health campaign with dramatic advertisements and messages would be appropriate. For example, the International Nurses Day of 2005 was focused upon the problem of counterfeit drugs.\textsuperscript{138} It included posters indicating that "Counterfeits Kill" distributed in clinics and facilities around the world; with twelve million nurses represented, such a campaign has the potential for significant public health impact.\textsuperscript{139}

\textsuperscript{136} The author at a Federation of State Medical Boards Patient Safety Task Force meeting notified the Federation of State Medical Boards representatives, including its President and Vice President for Legislative Affairs, about the Federation's program inclusion in S.334. Personal Communication with Jim Thompson, MD, President, and Lisa Robin, Vice President, Federation of State Medical Boards (May 12, 2005).


\textsuperscript{139} See International Council of Nurses, International Nurses Day, May 12, 2005,
Patients may also benefit from broad dissemination of simple consumer education cards. Checklists such as the SAFE DRUG checklist, available from the Partnership for Safe Medicines, are a step in the right direction.\textsuperscript{140}

Public health campaigns should also include public service messages broadcast through television and print media outlets. Ad Council efforts as well as prominent displays in high circulation magazines and newspapers of general interest are essential to raise awareness among consumers of the risks of fake or tainted medicines.

A public health campaign should also incorporate healthcare providers such as physicians and nurses. If physicians and nurses are not currently aware of the risks associated with counterfeit drugs, they may attribute therapeutic failure to human variation or patients dissembling about the source of their medicines.\textsuperscript{141} This lack of awareness derives from issues of parallel trade, since physicians and nurses generally do not ask where patients obtained their medications.\textsuperscript{142} Some efforts have been made to question patients in this regard by the International Council of Nurses and use of the SAFE DRUG checklist that has been developed and distributed to nurses on a small scale in the United States.\textsuperscript{143}

\textsuperscript{140} SAFE DRUG Checklist, \url{http://www.safemedicines.org/resources/SAFEDRUG.pdf}. To protect oneself against the potential for counterfeit drugs, patients should consider using samples, assessing drug Appearance, noting the body's feeling after taking the drug, evaluating one's response, contacting one's doctor if a suspected fake drug is detected, reporting any potential fake drug to the FDA and other regulatory agencies, making the drug unavailable so it will not be confused with legitimate forms, and gathering relevant information about the suspect drug for investigation. \textit{Id.}

\textsuperscript{141} \textit{See supra} notes 75-81 and accompanying texts (discussing additional concerns regarding detection).

\textsuperscript{142} \textit{Id.} Even if patients are asked by providers, they may be reluctant to disclose the source if it is from the Internet, an over-the-border sale, or other non-traditional source. \textit{Id.}

\textsuperscript{143} Partnership for Safe Medicines—Nursing SAFE DRUG checklist, \url{http://www.safemedicines.org/resources/001496.html}. This version has been disseminated to approximately 200 nurses in the San Diego region, and is being developed for dissemination by the International Council of Nurses in the future. Interview with James
Beyond educating patient and provider populations about the risks of counterfeit drugs and parallel importation, alert systems should also be implemented to provide information on detected fakes. Currently, the World Health Organization has started a rapid alert system, which, when fully implemented, may provide some benefit to governments for the subsequent dissemination to citizens of their respective countries. Perhaps more beneficial, the Partnership for Safe Medicines has created an email alert network system, allowing individuals to sign up for email alerts on counterfeit medicine warnings for any government alert or warning about fake drugs. Additionally, the FDA Counterfeit Alert Network issues counterfeit drug warnings to groups who then are responsible for warning their members. Programs such as these should coordinate and work with the media to disseminate relevant information to the general public.

B. Reporting Systems

As part of public policy addressing the potential for fake or tainted medicines, a broad-based reporting structure is essential. Patients, providers, public health staff, law enforcement, customs, industry, researchers, and others are all stakeholders who have

Class, Executive Dir. of the P'ship for Safe Meds., & Linda Carrier-Walker, Dir. of Communications & External Relations, Int'l Council of Nurses, in Geneva, Switzerland (Oct. 17, 2005).

144 See, e.g., Associated Press, WHO Launches Web-based System to Track Fake Drugs, CTV, May 3, 2005, http://www.ctv.ca/servlet/ArticleNews/story/CTVNews/1115117564266_14/?hub=Health. The system is essentially an information clearinghouse; reports sent, emailed, faxed and communicated to it are then disseminated to national authorities. Note, however, that the system does not reach individual consumers, primarily because certain part of the region to be served, Southeast Asia, have a technology deficit. For example, countries such as Burma only have 0.5 Internet users per 1,000, Cambodia has 2.2 per 1,000, and Laos has 2.7 per 1,000, compared with Singapore with 504 per 1,000 and Malaysia with 320 per 1,000. See Marwaan Macan-Markar, Fake Drugs in Poor Nations Worry Health Experts, CYBER DYARYO, May 16, 2005, http://www.cyberdyaryo.com/features/l2005_0516_03.htm.


147 Bryan A. Liang, Measuring the Impact of Counterfeit Drugs: Applying the Patient
treatment, investigation, and enforcement roles and who must be a part of this system.

The goal of such a reporting system is to provide information outlining the epidemiology of fake or tainted medicines and allowing effective public health and law enforcement interventions. These interventions would require information on location, patient diagnosis, harm, surrounding circumstances, patient outcome, and methods to remediate harm. Because counterfeit drugs are an international problem requiring an international solution, an effective reporting system coordinating and permitting international reporting and access to data is imperative.¹⁴⁸

Effective reporting systems require simple forms. Basic information to be collected would include:

- reporter name and contact information;
- location and date;
- patient diagnosis;
- suspect drug;
- drug source;
- sample available;
- patient harm;
- patient outcome;
- necessary treatment changes;
- any additional information.

To allow broad-based participation, the form should be user friendly and accessible for use and communication, including online, by fax, or by mail.¹⁴⁹

All reports should be sent to a single data repository site, at least regionally, to allow ease of analysis and cross-party

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¹⁴⁸ Id. Note that the United States and the European Union pledged cooperation and zero tolerance on counterfeits. See, e.g., EU, US pledge Zero Tolerance on Fakes, ASSOCIATED PRESS, Nov. 30, 2005, http://www.catiaworld.com/cwnews/view.asp?msgID=9084. However, no concrete details or efforts to share information or a reporting structure are yet evident.

¹⁴⁹ See Liang, supra note 147.
A single data site is important for integration of reports and avoidance of the widely disparate and fragmented condition that individual stakeholder reporting systems might create. Of course, fields on the data reporting form may be altered dependent upon the relevant stakeholder, so, for example, discovery of fake medicines by customs officials would allow for more detail in the drug source field. Drop down menus and other systems might be employed to further specify information by reporter.

A single reporting system also allows for rapid dissemination of information on suspect drugs by locale and facility to relevant stakeholders, such as patients, providers, and public health staff. Because reporting is broadened to include industry and broader government stakeholders such as customs officials, alert systems such as the World Health Organization rapid alert system, the Partnership for Safe Medicines SafeMeds email alert system, and the FDA alert system can be easily integrated and provide more information to relevant parties more quickly.

Additional benefits of such a reporting structure go beyond direct public health concerns. The epidemiology of counterfeits or tainted medications may identify geographic sites, the type of materials being used, and the drugs in question. This can provide information on the public economic burden faced by governments, as well as the private economic burden faced by providers, patients, and industries who must address the issue. It will also allow more effective tracing through database analysis, as well as effective application of geographic information systems (GIS); GIS analyses could provide thematic mapping for public health and investigation purposes. An integrated reporting

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150 A single data repository site would also make it easier for subsequent analysis of data. The Aviation Safety Reporting System, which is optimal in reporting to improve aviation safety, is a national database available for use by the government and the public, including research. This has improved safety tremendously since the system's inception. Its data has also been put in newsletter form for wider application and dissemination. Aviation Safety Reporting System, http://asrs.arc.nasa.gov/main_nf.htm.

151 See Liang, supra note 147.

152 Id.

153 Id.

154 Id.

155 Id. Note that, excipients of the fake or tainted drugs can be tracked using GIS,
structure will also raise joint awareness of the problem between stakeholders who may not have considered working together before.

C. Penalties

As noted above, penalties for counterfeiting and selling purportedly licit drugs are light. Immediate action by individual countries is needed to remedy problems with drug counterfeiting and the sale of counterfeit drugs. These countries need to implement changes in criminal statutes and make international consensus statements.¹⁵⁶

For example, criminal penalties for counterfeiting drugs must match those for illicit drug production. The harm associated with counterfeit drugs can be so dramatic and affect such a broad array of patients that consideration of life imprisonment is appropriate.¹⁵⁷ Forfeiture of assets and treble damages should also be considered in statutes that address counterfeit drug sale and manufacture.

Further, a limit on online pharmaceutical sales to those online pharmacies that have established their compliance with national safety standards would be beneficial.¹⁵⁸ Statutes characterizing Internet drug sales that are not in compliance with these standards as criminal trafficking of illicit drugs would send a clear message which may allow for source identification and illicit transport pathways across country lines supporting investigation and law enforcement efforts.

¹⁵⁶ Unfortunately, parallel trade locations such as Europe have not come forth with strong penalties or statements on the manufacture and sale of counterfeit drugs. Even reform efforts have been highly limited. See, e.g., Huw Jones, EU to Crack Down on Peddlers of Fake Products, REUTERS, July 12, 2005, http://today.reuters.com/News/CrisesArticle.aspx?storyId=L12615140 (describing a European Commission proposal for criminal organizations that commit fraud using fakes that threaten the public health should be imprisoned for at least four years and fined €100,000 to €200,000).

¹⁵⁷ Some jurisdictions have considered such a bill, e.g., Iowa. See David Pitt, Iowa House Passes Law Against Making Counterfeit Drugs, CEDAR FALLS COURIER, Apr. 22, 2005, http://www.wfcourier.com/articles/2005/04/22/news/breaking_news/doc4268d24b27870940659285.txt (reporting on a bill that penalizes involvement with the sale of counterfeit drugs resulting in death by life in prison).

to online purveyors of drugs that these sales will not be taken lightly.\textsuperscript{159} Highly publicized prosecutions and stiff penalties would drive at least some of these criminal operators out of the fake medicine business.

Enforcement of provider licensure laws is appropriate if providers are knowingly involved in the sale, distribution, or manufacture of counterfeit drugs. Thankfully, in a vast majority of U.S. cases, providers do not knowingly involve themselves in distributing fake medications. However, if it can be shown that providers are knowingly involved, they should not only be prosecuted under existing criminal law, but also should be brought up for disciplinary review by their respective professional boards. In this way, the panoply of penalties will include significant imprisonment, loss of assets, as well as potential loss of professional capacity.

\textit{D. Technology Investment}

Cooperative efforts, technological standardization, research including radio frequency identification tags, holograms, and other means must be engaged to ensure appropriate identification of valid drugs and their pedigrees.\textsuperscript{160} Research and development in this area should be supported by public and private investment, and should be developed internationally to harmonize their applicability across country and hemispheric lines.

However, technology is presently a limited solution to the problem of counterfeits associated with parallel trade.\textsuperscript{161} The state of the art of technology is not developed enough to support a public policy solution relying upon it. Indeed, the critical problem with current technology is that it is more useful as an inventory device than as a system to identify pedigree or authenticity of the

\textsuperscript{159} In concert with these penalties against the seller of fake or tainted drugs, penalties should also be considered against those who buy them. Although politically sensitive, the tremendous public health risks associated with Internet and other unsafe source purchases warrants the same kinds of penalties and protections akin to sales of dangerous products illicitly, such as firearms.

\textsuperscript{160} See supra note 133.

actual medicine itself.\textsuperscript{162} Additionally, since the two largest markets in the world—the United States and the European Union—allow repackaging of medicines, numerous weaknesses in current technological efforts undermine their present usefulness.\textsuperscript{163}

An investment in research and development of authentication and pedigree of the actual drugs—rather than packaging—should be an emphasis of public and private efforts. The current underdeveloped status of technological means substantiates the need to focus on this component of public policy to ensure safety of the drug supply. It should be emphasized, however, that technology can only be a part—not the entire—solution to the risks of fake medicines entering into the drug supply, since the creativity and adeptness of counterfeiters in the past has shown their ability to keep up with technological advances.

\textbf{VIII. Conclusion}

Parallel trade in pharmaceuticals creates significant public health risks. The world’s experience has illustrated the vulnerabilities that such trade creates, including, most importantly, the influx of counterfeits into the drug supply.

To combat this problem, a multifaceted, multidisciplinary approach is required that involves those who take the drugs, those who prescribe and monitor them, those who inspect them, and those who ensure their safety. This reality requires international cooperation and a global effort to effectively detect, detain, prosecute, and imprison those who would profit by cheating the public’s health. The producers and distributors of counterfeits are killers, and their presence should attract the attention, resources, and penalties appropriate for murderers.

Until there is a focused, sustained, and effective effort to successfully address the issues of counterfeit drugs in parallel trade, such a policy is inappropriate for the closed system in the United States, which has generally ensured a high-level of safety. We should not fall into the trap of believing that simply because one can buy legitimate drugs from an Internet seller through parallel trade means that all drugs so purchased are safe. The first,

\textsuperscript{162} Even then, there is significant error associated with technology use. \textit{See} Giacalone, \textit{supra} note 130.

\textsuperscript{163} \textit{See} Giacalone, \textit{supra} note 130 and accompanying text.
tenth, or hundredth medicine taken may be real, or it at least may not be fatal. But it takes only one event that harms or kills to show the risk of such a policy; and by then, it will be too late.