

Fade to Black: Importation and Counterfeit Drugs

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I. INTRODUCTION

Americans rely extensively upon prescription medications to maintain health and quality of life. According to the National Center for Health Statistics, in 2002, at least 1.5 billion drugs were prescribed to patients in physician offices, 196 million in US emergency departments, and 140 million in outpatient settings.¹ Almost two-thirds of visits to physician offices and hospital outpatient departments had at least one drug associated with the visit, and 7% of visits had five or more drugs.² In 2004, US pharmacies dispensed over 3.5 billion prescriptions to patients.³ Estimates indicate that annual expenditures for prescription drugs in the US top \$230 billion dollars each year⁴—and there is every indication that these numbers will only increase.⁵

Prescription drug use is not simply associated with acute provider visits but is a standard part of US life. At least 44% of all citizens report using prescription drugs

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¹ National Center for Health Statistics, Therapeutic Drug Use, www.cdc.gov/nchs/fastats/drugs.htm (last visited June 30, 2005).

² *Id.*

³ IMS Health, U.S. Prescription Activity by Channel, 2004, http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695974_68913551,00.html (last visited June 30, 2005).

⁴ IMS Health, U.S. Purchase Activity by Channel, 2004, http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695983_69891354,00.html (last visited June 30, 2005).

⁵ *See id.* (indicating that there was an 8% growth in sales last year).

in the last month, and, indeed, 17% reported using at least three or more.⁶ Seniors use a large fraction of these medicines. Greater than 80% of seniors use at least one drug, 50% report taking at least three prescription drugs, and at least 20% of seniors take at least five prescription medications.⁷ Although seniors account for only 13% of the population, as patients they account for more than one third of all prescriptions, and as payers they account for more than 40% of each dollar spent on drugs each year.⁸ It is estimated that seniors alone spent more than \$70 billion on prescription medicines in 2005.⁹

Prescription medications have become a powerful tool in the medical arsenal against disease and promotion of health and quality of life. Yet the success of prescription drugs and their extensive use has attracted unsavory characters interested in exploiting vulnerable patients and the market for medicines. These opportunistic creatures introduce and peddle counterfeit drugs through vulnerabilities in the drug distribution system. In the United States, counterfeits are a growing problem, but our closed, domestic system has so far maintained a high level of safety.¹⁰ However, the rest of the world has and does experience increasing problems with fake medicines, in great part due to extensive movement of drugs in and out of countries through licit and illicit importation.¹¹ Hence, without extensive new infrastructures involving safety systems, appropriate laws and regulations, investment in technology, and coordination of these components, allowing large scale importation of drugs into the United States could very well import other countries' counterfeit drug problems into our own.

This paper reviews some of the issues associated with counterfeit drugs and drug importation. In Part II, the characteristics of counterfeit drugs are reviewed, including their scope, known epidemiology, associated types of harm, and reasons for production and sale. In Part III, the interactions of counterfeits and importation are outlined, including the international experience and policy concerns that result. The Pharmaceutical Market Access and Drug Safety Act of 2005, often known as the Dorgan bill, is also assessed. In Part IV, issues associated with Internet pharmacies and accountability are discussed. In Part V, thoughts on reform are presented and proposed, and deeper issues of price and research and development, focusing upon international cooperation, are considered. Finally, in Part VI, the paper concludes.

⁶ NATIONAL CENTER FOR HEALTH STATISTICS, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, CENTERS FOR DISEASE CONTROL AND PREVENTION, PUBL'N NO.2004-1232, HEALTH, UNITED STATES, 2004 50-53 (2004), <http://www.cdc.gov/nchs/data/hus/hus04.pdf>.

⁷ *Id.*

⁸ FAMILIES USA, COST OVERDOSE: GROWTH IN DRUG SPENDING FOR THE ELDERLY, 1992-2010 2 (July 2000), available at <http://www.familiesusa.org/assets/pdfs/drugod852b.pdf>.

⁹ *Id.* at 4. Since these estimates were performed in 2000, it is likely that cost will be even higher.

¹⁰ HHS TASK FORCE ON DRUG IMPORTATION, US DEP'T OF HEALTH AND HUMAN SERVICES, 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 import drugs for domestic use are the manufacturers themselves.

¹¹ See, e.g., Helen Frankish, *WHO Steps Up Campaign on Counterfeit Drugs*, 362 LANCET 1730 (2003); Liza Gibson, *Drug Regulators Study Global Treaty to Tackle Counterfeit Drugs*, 328 BRIT. MED. J. 486 (2004); Paul Rudolf & Ilisa Bernstein, *Counterfeit Drugs*, 350 NEW ENG. J. MED. 1384 (2004); Albert Wertheimer et al., *Counterfeit Pharmaceuticals: Current Status and Future Projections*, 43 J. AM. PHARM. ASS'N. 710 (2003); INTERNATIONAL COUNCIL OF NURSES, NURSES FOR PATIENT SAFETY: TARGETING COUNTERFEIT AND SUBSTANDARD MEDICINES (2005), <http://www.icn.ch/indkit2005.pdf>.

II. COUNTERFEITS

A. SCOPE

Counterfeit drugs are a worldwide problem. The World Health Organization (WHO) has reported that a significant fraction of the world's drug supply is counterfeit.¹² While the scope of the problem is unknown, the WHO estimates that up to 60% of drugs in some developing countries are fake, and up to 20% in some developed countries are fake.¹³ Overall, approximately 10-15% of all drugs sold in the world are counterfeit.¹⁴ Through importation and reimportation, fake drugs enter into country supplies and end up in drug stores,¹⁵ and, ultimately, in patients who ingest or are injected with them.¹⁶

Although the United States has not experienced the degree of counterfeit saturation that other countries have, it has not been immune. For example, in 2003, 200,000 bottles of Lipitor, a cholesterol drug and one of the world's best selling medicines, were recalled due to the discovery that they were counterfeit.¹⁷ These drugs were a mixture of fake drugs manufactured in Central America, mixed with South American versions of the actual drug, and the illegal importation and sale of both into the US.¹⁸ In the summer of that same year, blitz inspections by government officials of foreign drug imports at US international mail facilities found that 88% were unapproved, may have been stored inappropriately, and had safety issues.¹⁹ In addition, a 2003 sales estimate of counterfeit or tainted prescription drugs sold in the United States alone was \$200 million—a seven-fold increase from the previous year.²⁰ In 2004, FDA officials discovered that a large proportion of Mexican drugs imported by US citizens were fake,²¹ and in May 2005, the FDA issued warnings on

¹² World Health Organization, Fact Sheet No. 275: Substandard and Counterfeit Medicines (Nov. 2003), <http://www.who.int/mediacentre/factsheets/2003/fs275/en> [hereinafter Fact Sheet No. 275].

¹³ *Id.* In some cases, such as drugs to treat malaria, up to 90% have been found to be fake. See Dr Shigeru Omi, WHO Regional Director for the Western Pacific, Talks at the Fifty-sixth Session of the Regional Committee, PR NEWSWIRE, (Sept. 19, 2005), available at <http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=104&STORY=/www/story/09-19-2005/0004109770&EDATE=>.

¹⁴ Fact Sheet No. 275, *supra* note 12 (10%); Robert Cockburn et al., *The Global Threat of Counterfeit Drugs: Why Industry and Governments Must Communicate the Dangers*, 2 PLoS MEDICINE 0302, 0302 (Apr. 2005), available at http://medicine.plosjournals.org/archive/1549-1676/2/4/pdf/10.1371_journal.pmed.0020100-S.pdf (15%).

¹⁵ "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 Kalette, *Florida Authorities Arrest 10 in Massive Internet Drug Sweep*, DAYTONA BEACH NEWS, July 16, 2005, available at <http://www.americaputmeoutofbusiness.com/news-july-16-05-001.php> (describing Internet pharmacy selling millions of dollars of drugs illegally after creating shell pharmacies).

¹⁶ World Health Organization, Essential Drugs and Medicines Policy (June 28, 2004), <http://www.who.int/mediacentre/factsheets/fs275/en/>.

¹⁷ See *FDA Kicks Off Crackdown on Rising Rate of Counterfeit Drugs: Recalls of Bottles of Fake Lipitor Highlights Problem Infecting Nation's Medicine Supply*, CHARLESTON POST & COURIER, July 17, 2003, available at <http://www.medicalhelpnet.com/forums/viewtopic.php?p=6996>

¹⁸ *Federal Authorities Cease Sale and Distribution of Counterfeit Lipitor*, FDA NEWS, Aug. 31, 2005, available at <http://www.fda.gov/bbs/topics/news/2005/NEW01228.html>

¹⁹ TASK FORCE, *supra* note 10, at 13.

²⁰ Don Oldenburg, *Raising the Alarm on Counterfeit Drugs*, WASH. POST, Apr. 5, 2005, at C9 (quoting most recent figures from the Pharmaceutical Security Institute).

²¹ Food and Drug Administration, U.S. Dep't. of Health and Human Services, FDA Talk Paper T04-28: FDA Warns Consumers About Counterfeit Drugs Purchased in Mexico, (July 30, 2004), available at <http://www.fda.gov/bbs/topics/ANSWERS/2004/ANS01303.html>. [hereinafter

fake Lipitor, Viagra, and an unapproved osteoporosis drug being imported over the Mexican border by US citizens.²² In addition, a 2005 story in *Business Week* highlighted the tremendous increase and market in counterfeit goods worldwide, including counterfeit medicines.²³ Further, the Pharmaceutical Security Institute, a nonprofit trade association group, reported in May 2005 that the United States experienced the greatest number of problems in counterfeiting, theft, and drug diversion—for a second year in a row.²⁴ Also, Sen. Charles Schumer (D-N.Y.) recently indicated that in New York alone, there were nearly 100,000 instances of fake drugs used to fill prescriptions.²⁵

As evidence regarding the problem of counterfeit drugs in this country began mounting, the US Department of Health and Human Services launched an investigation into the issue under mandates of the Medicare Modernization Act.²⁶ In December 2004, it issued a report detailing significant security issues associated with drug importation and counterfeit drugs.²⁷ One of the most alarming issues involved detection of imported counterfeit drugs. Investigators noted that there are only 16.9 full time FDA employees responsible for covering all international mail facilities in the US to search for incoming counterfeit drugs—and that is not their only duty,²⁸ with 20 to 30 million packages entering the US each year through the US postal service,²⁹ resources devoted to detecting problematic drugs are not anywhere near adequate.

Additional information from the report is equally dismal. The high degree of Internet sales, the costs associated to ensure safety of drugs imported by individuals, the limited savings from a formalized importation policy of 1% or less, high technology costs to protect the drug supply, misperceptions about imported drug prices compared with the US, and the potential reduction in future development of

FDA Talk Paper]. Drug purchases by US citizens from Mexico is particularly insidious. The focus over the border is now on pharmaceutical sales to US customers, virtually all medicines are available, and the appearance of those selling the product lend confidence to the transaction. *See* Matt Taibbi, *Pill City*, *ROLLING STONE*, Feb. 24, 2005, at 47 (describing journalist experience in obtaining medicines, including morphine derivatives, Ritalin, and other drugs, and experiencing “being ripped off ... my battering average for counterfeits is about .350.”). *Id.* at 49. Additionally, one can purchase “medicines” that do not exist: the author of this article traveled to Tijuana, Mexico in February 2005, and asked for “generic Viagra”. All six pharmacies were able to sell this product. However, there is no such thing as “generic Viagra”. Further, medicines such as flu vaccine were also available. Upon purchase, the vaccine was at room temperature; yet flu vaccine must be kept refrigerated to maintain activity.

²² *See* FDA Talk Paper, *supra* note 21.

²³ Frederik Balfour, *Fakes!*, *BUS. WEEK*, Feb. 7, 2005, available at http://businessweek.com/magazine/content/05_06/b3919001_mz001.htm.

²⁴ Julie Appleby, *Stolen, Counterfeit Drug Problems Rise*, *USA TODAY*, May 10, 2005, available at http://www.usatoday.com/news/health/2005-05-10-counterfeit-drugs-usat_x.htm.

²⁵ Associated Press, *Counterfeit Drug Problem Getting More Attention*, *WWSB ABC 7*, Aug. 7, 2005, available at <http://www.wwsb.com/frameset.asp?page=http://www.wwsb.com/news/details.asp?id=32963> (last visited August 10, 2005).

²⁶ Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended in scattered sections of 42 U.S.C.).

²⁷ TASK FORCE, *supra* note 10.

²⁸ *Id.* at 56 fig. 5.3.

²⁹ This does not count other delivery mechanisms such as Federal Express, UPS, etc. *See* MARV 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 8* (Oct. 18-19, 2004), <http://www.ashp.org/practicemanager/LeadershipDev/2004LeadershipSummary.pdf>.

new drugs all create issues of practicality and desirability that make the importation decision and policy in the context of counterfeits highly complex.³⁰

The FDA estimates that ~1% or less of drugs in the United States are tainted or counterfeit.³¹ Assuming only one tenth of one percent of drugs in the US are affected, in combination with the WHO estimates,³² this still means that more than 3.5 million to 350 million US prescriptions may be potentially affected by counterfeit drugs each year.

B. TYPES

Early incidents of counterfeit drugs primarily targeted the category of “lifestyle” drugs: for example, Viagra.³³ In some quarters, there was very little sympathy for these victims because of the perceived “lifestyle” nature of these drugs (as opposed to therapeutic medications). Unfortunately, counterfeiters have since expanded their lucrative markets. Recent investigations have turned up counterfeit AIDS/HIV therapy, over-the-counter pain medications, antibiotics, insulin, cholesterol drugs, hormone replacement therapy, flu medications, cancer drugs, anti-arthritis drugs, cardiac drugs, anti-parasitic drugs, antihistamines, and many more.³⁴ The counterfeit market has burgeoned and matured: counterfeits now span the spectrum from lifestyle drugs to lifesaving drugs. It is likely that all citizens are potentially affected.

Harm occurs in at least three ways. First, if the fake drug contains the wrong drug, the patient is not treated for the disease he or she has. This can occur when, for example, vials (in some cases purchased on online auction sites like Ebay)³⁵ are

³⁰ TASK FORCE, *supra* note 10, at xii-xiii. Note that the Task Force report indicated middlemen would garner most of the savings; other analysis has also concluded that consumers will have limited savings associated with importation. See CONGRESSIONAL BUDGET OFFICE, ECONOMIC AND BUDGET ISSUE BRIEF: WOULD PRESCRIPTION DRUG IMPORTATION REDUCE U.S. SPENDING? (Apr. 29, 2004), <http://www.cbo.gov/ftpdocs/54xx/doc5406/04-29-PrescriptionDrugs.pdf>. Parallel import experience in Europe indicates similar pricing dynamics, with the parallel traders gaining the benefits of differential pricing. See, e.g., Panos Kanavos et al., *The Economic Impact of Pharmaceutical Parallel Trade in the European Union Member States: A Stakeholder Analysis* (London School of Economics, Working Paper, 2004), executive summary available at <http://www.lse.ac.uk/collections/LSEHealthAndSocialCare/pdf/Workingpapers/executivesummary.pdf>. Apparently, any savings that is occurring now is being reduced annually, perhaps on the basis of Canadian suppliers seeking economic rents from US consumers. See Theresa Agovino, *Savings from Canada Drug Purchasing Fall*, WASH. POST, Jan. 5, 2005, available at <http://www.wtopnews.com/index.php?sid=380318&nid=106#> (describing study by PharmacyChecker.com showing a drop of price discounts between Canada and the US from 38% in 2003 to 29% in 2004). Further, it is difficult to determine actual price differentials because of the varying methodologies being used to assess price, including assessment of prices charged by manufacturers, consumer prices, insurer/HMO prices, government prices, and the particular drugs chosen for comparison. See, e.g., Benjamin A. Drabiak, *Reimportation of Prescription Drugs: Long-lasting Relief or a Short-term Analgesic?* 4 WASH. U. GLOBAL STUDIES L. REV. 135, 143-44 (2005). Other factors are also involved, such as the litigation system differences between countries. See *id.* at 148-150.

³¹ Rudolf & Bernstein, *supra* note 11.

³² Cockburn et al., *The Global Threat of Counterfeit Drugs*, *supra* note 14.

³³ Ben Hirschler, *Criminals Make Killing from Fake Drugs*, REUTERS HEALTH, Aug. 1, 2005, available at http://www.ucsfhealth.org/childrens/health_library/reuters/2005/08/20050801elin017.html (describing the ubiquity of counterfeit ‘lifestyle’ drugs).

³⁴ Cockburn et al., *The Global Threat of Counterfeit Drugs*, *supra* note 14.

³⁵ LEW KONTNIK, PHARMACEUTICAL COUNTERFEITING: PREVENTING THE PERFECT CRIME 2 (2004), http://www.fffenterprises.com/web_files/fff_wht_ppr_111804.pdf. Note that pharmaceutical manufacturing and labeling equipment is also available on Ebay; see, e.g., GLOBALOPTIONS INC., AN ANALYSIS OF TERRORIST THREATS TO THE AMERICAN MEDICINE SUPPLY 29-30 (2003), available at

re-labeled with a fake label as another, more expensive antibiotic with different bacterial coverage than the one originally prescribed, or when the drug has become inactive due to expiration³⁶ or poor storage. Wrong or ineffective drugs not only fail to help the patient get better but also contribute to the increase in antibiotic resistance of bacterial pathogens, making infections harder to fight. In addition, fake drugs also contribute to the mistaken impression that antibiotic resistant strains are present due to lack of therapeutic effect of first-line therapies, resulting in use of stronger therapies, once again contributing to creating pathogen resistance to antibiotics.

Secondly, the patient may get the wrong concentration or dose with a counterfeit. This has occurred with Botox treatments, where a physician was supplied with a research version of Botox,³⁷ which is much more concentrated than that utilized for anti-wrinkle treatment and not intended for human use. It resulted in respiratory paralysis and near death for several patients, including the physician who was using it himself.³⁸ Another example was a cancer patient who needed red blood cell promoting Erythropoietin, which virtually all patients require after chemotherapy because of the latter's side effect of causing severe anemia.³⁹ Criminals sold a form of the IV drug diluted with bacterially-contaminated water, which was then injected directly into the patient.⁴⁰

The third common method of harm results when the fake drug has no active ingredients and indeed may have harmful ingredients added to make the drug more realistic. In these circumstances, patients are not only harmed by not being treated, they are sometimes killed by materials used to make the fake drug. Counterfeiters have introduced bacteria-laced water as noted above, colored dye, powdered cement,⁴¹ toxic yellow road paint, floor wax, boric acid⁴² (the latter used commonly to kill cockroaches), and, horrifyingly, antifreeze. Over 500 children died from ingesting what their parents thought was cough syrup, but was instead counterfeit medicine tainted with ethylene glycol⁴³ before the deadly drug was discovered and

<http://www.globaloptions.com/booktext2003.pdf>. Ebay has been found to allow sales of counterfeit drugs such as steroids and Viagra. See *The £4billion Car Boot Sale*, NEWS & STAR (UK), August 20, 2005, available at <http://www.newsandstar.co.uk/familylife/viewarticle.aspx?id=277293>.

³⁶ See Kontnik, *supra* note 35.

³⁷ See generally U.S. Dep't. of Justice, *Professor of Ophthalmology/Director of Occulo-Facial Plastic Surgery at University of Kentucky Charged in Fake Botox Prosecution* (Mar. 22, 2005), <http://www.usdoj.gov/usao/fls/BakerRobertMD.html>.

³⁸ *Id.*

³⁹ Rudolf & Bernstein, *supra* note 11.

⁴⁰ Catherine Wilson, *Two Florida Men Sentenced for Drug Scam*, AP NEWS, Aug. 29, 2003, available at: <http://www.aegis.com/news/ap/2003/AP030846.html>. See also Chris Hansen, *Inside the World of Counterfeit Drugs*, NBC DATELINE, June 4, 2006, available at: <http://www.msnbc.msn.com/id/13137839/> (last visited June 11, 2006) (describing drug dilution case and broader problem of counterfeit drugs in the US).

⁴¹ See Charles W. Schmidt, *Phony Pharm*, MOD. DRUG DISCOVERY, Nov. 2002, at 27.

⁴² See *Continuing Concerns Over Imported Pharmaceuticals: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 107th Cong. (2001) (Prepared Testimony of James Christian, Vice President and Head of Security, Novartis International AG). available at: <http://energycommerce.house.gov/107/hearings/06072001Hearing267/Christian404print.htm> (discussing additional deaths).

⁴³ Ethylene glycol is the chemical name for antifreeze. The substance is sweet so detection of its presence in artificially sweetened cough syrup is almost impossible. See Agency for Toxic Substances and Disease Registry, *Medical Management Guidelines for Ethylene Glycol*, <http://www.atsdr.cdc.gov/MHMI/mmg96.html> (last visited Apr. 19, 2006).

destroyed.⁴⁴ Other similarly shocking and horrendous fake drug cases include counterfeit inhalers for pediatric cystic fibrosis patients that were contaminated with bacteria being directly introduced into the children's lungs,⁴⁵ and injected cancer drugs that were only vials filled with tap water.⁴⁶

One of the most insidious means of selling counterfeits is salting. Salting occurs when legitimate drugs or fakes with some active ingredient—which are often imported from other countries or have expired—are mixed or “salted” with fake versions of the drug. In this way, even if patients, pharmacists, or government authorities are attempting to detect counterfeits, these fake drugs may elude detection due to a legitimate sample or fake with the active molecule being pulled for testing.⁴⁷

C. REASONS

1. Cash, Costs, and Penalties

The primary reason for the explosion of the counterfeit market is simple: money. It is estimated by WHO and the FDA that worldwide sales of counterfeit drugs represent between \$32 billion and \$35 billion annually;⁴⁸ that is \$88 to \$96 million in sales *each day*. Related to this incredible cash flow, the FDA and international government authorities warn that counterfeit drug sales are linked to funding of well organized international criminal operations and terrorist activities, including those of Hezbollah and Al Qaeda,⁴⁹ as well as countries who may sponsor

⁴⁴ Fact Sheet No. 275, *supra* note 13.

⁴⁵ See *Attorney General Sues Tampa Couple Over Fake Cystic Fibrosis Drug*, FOX 35 NEWS, Apr. 8, 2005, http://www.wofl.com/_ezpost/data/14958.shtml.

⁴⁶ See Elizabeth Cady Brown, *Pharmaceutical Fakery: Counterfeit Drugs Threaten Patients' Health*, LONG ISLAND PRESS, June 9, 2005, available at http://www.longislandpress.com/?cp=188&show=article&a_id=4250; See also Oldenburg, *supra* note 20, at C9 (Discovery of an AIDS patient's fake growth hormone treatment after the injection left a burning sensation.). Small markets have also been found to sell tainted and counterfeit drugs, particularly in minority communities. See, e.g., Lisa Reyes, *Prescription Drugs Sold Illegally*, NEWS CHANNEL 14, July 20, 2005, http://www.news14charlotte.com/content/local_news/?ArlD=98236&SecID=2. Other recent examples of drugs that have been counterfeited include Lipitor, Procrit, Neupogen, Viagra, and Zyprexa. Packaging and materials were of high quality. See Rudolf & Bernstein, *supra* note 11, at 1385.

⁴⁷ See, e.g., Susan Todd, *Florida Man Admits Sale of Fake Lipitor*, STAR-LEDGER (NJ), Feb. 10, 2005 (describing Lipitor salting by convicted cocaine traffickers).

⁴⁸ Cockburn et al., *The Global Threat of Counterfeit Drugs*, *supra* note 14. See generally Bryan A. Liang, *Parallel Trade in Pharmaceuticals: Injecting the Counterfeit Element into the Public Health*, 31 N.C. J. INT'L L. & COM. REG. (2006), forthcoming (reviewing issues of profits and low penalties for drug counterfeiters).

⁴⁹ See, e.g., GLOBALOPTIONS INC., *supra* note 35, at 13-14, 69-70, 159-165 (2003); Celia Hall, *Internet Fuels Boom in Counterfeit Drugs*, TELEGRAPH (UK), Aug. 16, 2005 ("Much of the [counterfeit drug] supply comes from India and Asia and there are signs that the counterfeit medicines trade is linking up with organi[z]ed crime. 'If people buy these drugs, they should be aware of the risk they are taking as well as being aware they may be supporting organi[z]ed crime or terrorism.'" (quoting Naeem Ahmed, head of medicines intelligence, UK Medicines and Healthcare Products Regulatory Agency)). Hirschler, *supra* note 33 ("given the low production costs[, counterfeit drug production] is a hugely lucrative trade and some criminals now prefer it to narcotics"); Mark Sherman, *87 Charged in Counterfeit Drugs, Money, Cigarettes*, CHI. TRIBUNE, Aug. 22, 2005 (describing crime bust of counterfeit drugs, money, cigarettes, and consumer products); Gavin Phipps, *Counterfeit Pills are Not Placebos: Many People Regularly Take Prescription Pills. Unfortunately, It is Quite Likely the Pills are Not What They are Supposed to Be*, TAIPEI TIMES, August 21, 2005 (describing Taiwan's fake drug problem with up to 30% of some drugs counterfeit and involvement of organized crime.); and Elizabeth Thompson, *Counterfeit Items Pose Real Threat to Public*, MONTREAL GAZETTE, Sept.

these activities, such as North Korea.⁵⁰ The drug supply has also been identified by the FDA as a target for terrorists.⁵¹

It is also easy to produce these drugs. Making illicit drugs such as heroin and cocaine is a very difficult, expensive, and highly risky activity.⁵² Counterfeit licit drugs, on the other hand, are cheap, financially lucrative, and low risk.⁵³ Nefarious producers can use unskilled workers, and need only make drugs that *appear* authentic; they do not have to work. A fake pill may cost less than \$0.01 to make, but can be sold for \$0.30,⁵⁴ and that is still cheaper than the actual drug. In addition, the risk and cost of selling licit drugs is much lower than that for illicit drugs.⁵⁵

Part of the lure of counterfeit production is also related to pressure from the United States and domestic country governments on illicit drug production. In Latin American countries, where a significant amount of cocaine and heroin production occurs, governments have passed increasingly stringent laws.⁵⁶ Hence, such production may result in 10-15 years in prison.⁵⁷ Yet, laws regulating the production of fake, licit drugs have not been strengthened to reflect the gravity of the harm. Penalties are light—often only 6 months in jail, and individuals caught can be out on bail in just a few days.⁵⁸ Therefore, an unintended consequence of creating appropriate penalties for drug lords caught making illegal drugs is a business reevaluation that has shifted production to a much cheaper, less risky, and more lucrative product: counterfeit legal drugs. Hence, Latin America has become a source and is itself awash in counterfeit drugs.⁵⁹

6, 2005 (discussing influx of counterfeits into Canada, including counterfeit drugs, leading the US to place Canada on its watch list “in large part because the United States believes [Canada] is not doing enough to stop counterfeits at the border and [Canada] is being used as a transit point for goods destined for the U.S. market”). Further, Canada Border Services Agency officials do not have the right to search shipments for goods bearing a counterfeit trademark, nor can it alert the holders of the intellectual property rights there is an actual or potential trademark infringement. *Id.* See also INTERNATIONAL ANTICOUNTERFEITING COALITION, WHITE PAPER: THE NEGATIVE CONSEQUENCES OF INTERNATIONAL INTELLECTUAL PROPERTY THEFT: ECONOMIC HARM, THREATS TO THE PUBLIC HEALTH AND SAFETY, AND LINKS TO ORGANIZED CRIME AND TERRORIST ORGANIZATIONS (Jan. 2005), <http://www.iacc.org/WhitePaper.pdf> (describing product piracy effects, including counterfeit drugs, on US economy and public health).

⁵⁰ See Jay Solomon & Gordon Fairclough, *North Korea's Counterfeit Goods Targeted: US Seeks to Curb Illicit Business in Cigarettes, Drugs, Currency to Augment Diplomacy*, WALL ST. J., June 1, at A4. It is interesting to note that at least one commentator indicates that drug companies should not subsidize undemocratic regimes through low drug prices. See Philip G. Griffiths, *Dying for Drugs: Drug Companies Should Not Have to Subsidize Incompetent Governments* [letter], 327 BRIT. MED. J. 7410 (2003).

⁵¹ Associated Press, *FDA: Al-Qaida Could Poison Medicines*, Aug. 12, 2004, <http://msnbc.msn.com/id/5682351>; *Fake Drugs Are Real Dangers for U.S. Consumers*, PRNEWswire, Aug. 13, 2004, available at <http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=109&STORY=/www/story/08-13-2004/0002231340&EDATE=> (last visited August 30, 2004).

⁵² Kerry Capell et al., *What's in That Pill?*, BUS. WEEK, June 18, 2001, available at www.businessweek.com/magazine/content/01_25/b3737153.htm

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ For example, estimates in Peru are that 15-20% of the drugs sold in the country are fake, stolen, or have expired. See Encarna Nunez-Diaz, *Minsa Reports That 20% of Medicines Sold in Peru Are Counterfeit*, WORLD MARKETS ANALYSIS, Apr. 14, 2005. Indeed, because of the limited enforcement budget, it is estimated that 30% of the 6,000 pharmacies in Lima, the capital, are unlicensed. Compounding the problem is that one-fifth of the medicines trade occurs in the “informal

Penalties for counterfeit drugs in the United States are also weak: for example, counterfeiting a trademark may get the perpetrator 10 years in jail,⁶⁰ but counterfeiting a drug subjects him or her to only up to 3 years in prison.⁶¹ In some cases, no jail time is given.⁶² Such perverse incentives are akin to the effects in Latin America⁶³ that only lightly punish counterfeit drug production. Hence, former convicted cocaine traffickers have entered into the US market to sell counterfeits. For example, two who were caught, Domingo Gonzalez and Julio Cruz, led a multi-million dollar counterfeit ring that included sale of at least 4 million cholesterol medicine tablets and generated greater than \$10 million in sales.⁶⁴ Other cases show how easy it is to get involved in the counterfeit trade.⁶⁵

2. Gray Market

A tremendous part of the United States' problem with counterfeit drugs results from the "gray market." Traditionally, 90% of prescription drugs move from the manufacturer to large wholesalers then directly to the pharmacies in the community or other facilities such as hospitals and nursing homes. This market is dominated by three large bulk wholesalers: Amerisource Bergen, Cardinal Health, and McKesson Corporation.⁶⁶ However, up to 10% of drugs pass through the gray market, represented by thousands of interactions between larger and smaller wholesalers and providers.⁶⁷ This secondary "gray" market is the vulnerability where counterfeits can enter.⁶⁸

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 pharmaceutical and other products. See Martin Krause, *A New Balance on Counterfeit Goods*, TECH CENTRAL STATION, Aug. 22, 2005, <http://www.techcentralstation.com/082105C.html>.

⁶⁰ 18 U.S.C. §2320 (2000)

⁶¹ U.S. Food and Drug Administration, *Protecting Consumers from Counterfeit Drugs*, FDA CONSUMER MAG, May-June 2004, available at http://www.fda.gov/fdac/features/2004/304_drug.html; see also Douglas W. Stearn, *Deterring the Importation of Counterfeit Pharmaceutical Products*, 59 FOOD & DRUG L.J. 537, 549-550 (2004) (discussing ramifications of limited criminal penalties and extensive complexity to prosecute illegal importers).

⁶² See, e.g., *L.A. Man Sentenced in Fake Viagra Case*, ASSOCIATED PRESS, May 17, 2005, available at <http://dailynews.muzi.com/news/ll/english/1363157.shtml?cc=25506> (man caught smuggling and manufacturing counterfeit Viagra given six months home detention and 2,500 hours community service as penalty).

⁶³ Light punishments for counterfeiters have resulted in problems in the UK as well. See *infra* notes 90-94 and accompanying text.

⁶⁴ Todd, *supra* note 47, at 60; see also Cristina C. Birondo, *Drive vs. Fake Drugs*, THE FREEMAN (Philippines), July 10, 2005, available at <http://www.thefreeman.com/local/story-20050710-32228.html> (describing Philippines's Councilor Arsenio Pacaña who warns that illicit drug lords have moved into counterfeit drug production).

⁶⁵ See Bob LaMendola & Sally Kestin, *Former Convicts Try a Safer Venture: Pharmaceuticals*, SUN-SENTINEL (Florida), May 26, 2003, at 1A (outlining numerous cases of convicted felons obtaining state licenses to distribute medications and selling counterfeit drugs).

⁶⁶ Bernadine Healy, *Mean-Street Medicine*, U.S. NEWS & WORLD REPORT, May 16, 2005, at 56.

⁶⁷ GLOBALOPTIONS INC., *supra* note 35, at 21-22; Laura A. Willard, *Allocating Responsibility for Counterfeit Prescription Drugs*, 8 J. BIOLAW & BUS. 41 (2005); Healy, *supra* note 66, at 56; Bette Hileman, *Counterfeit Drugs*, CHEM. & ENG. NEWS, Nov. 10, 2003, at 36.

⁶⁸ Jeff Siegel, *Secondary Wholesalers: The Ghost in the Machine*, PHARMACEUTICAL COMMERCE, Dec. 27, 2005, available at <http://www.pharmaceuticalcommerce.com/frontEnd/main.php?idSeccion =214> (noting that there are legitimate dealers in the secondary market, but that trading outside of these legitimate parties is the gray market that enables fakes to enter); See Jenn Abelson, *CVS Takes Step to Keep Fake Drugs off Shelves: Firm Tightens Criteria for Picking Suppliers*, BOSTON GLOBE, May 25, 2005, available at

Theoretically, bulk wholesalers sell directly to customers like consumer and hospital pharmacies, who then dispense these drugs to patients. However, in reality, the “Big Three” wholesalers sometimes buy back drugs from the smaller secondary wholesalers to cover short term shortages. Pharmacies and others sell stock amongst themselves and to and through secondary wholesalers when they need cash flow; excess supplies with impending expirations are sold between and among large and small wholesalers, pharmacies, hospitals, and other providers; bulk drugs are sold to repackagers with other parties in-between to create consumer-level sales products; and arbitrage activities result in prescription medicines passing through numerous wholesaler, retailer, and/or repackager hands before reaching the final seller and the patient.⁶⁹

Gray market sales regulation is fractionated. Distribution, repackaging, dispensing, and returns of pharmaceuticals by purchasers are governed by state law,⁷⁰ often with few requirements and inadequate support for staffing for inspection and enforcement. Drug approval and manufacturing is governed by federal law, often with limited coordination with state activities.⁷¹ Consequently, many holes exist within the safety net of pharmaceutical distribution. This highly convoluted gray market allows parties peddling fake drugs to slip their products into the distribution chain, and ultimately, into the patient who buys and takes the tainted medication.⁷²

3. Detection

Another problem that allows for such ease in action is the difficulty of counterfeit detection. Passing off counterfeit drugs is indeed the perfect crime.⁷³

http://www.boston.com/business/articles/2005/05/25/cvs_takes_step_to_keep_fake_drugs_off_shelves/ (discussing secondary market and efforts of drug distributors to limit counterfeit drugs in supply chain); See also Mary Pat Flaherty & Gilbert M. Gal, *Lax System Allows Criminals to Invade the Supply Chain*, WASH. POST, Oct. 22, 2003, at A01 (noting all of the “big three” pharmaceutical distributors have been affected by counterfeit drug sales).

⁶⁹ Kontnik, *supra* note 35, at 5-6; See Susannah Patton, *Cracks in the Pharmaceutical Supply Chain*, BIO-ITWORLD.COM, January 18, 2006, <http://www.bio-itworld.com/newsitems/2006/january/11-18-06-news-supply-chain> (discussing the trade of pharmaceuticals between numerous and often unknown sources in the secondary market); see also Flaherty & Gilbert M. Gal, *supra* note 68 (discussing the “numerous middlemen” who handle pharmaceuticals during their “circuitous route” and noting that even the “big three” distributors have unknowingly purchased counterfeits).

⁷⁰ Kontnik, *supra* note 35, at 5.

⁷¹ See *id.*

⁷² *Id.* at 5-6. Note that some entities have indicated they will no longer accept drugs from wholesalers who use middlemen. Abelsen, *supra* note 68. Elliot Spitzer, the Attorney General of New York, has also opened investigations of wholesalers dealing in the gray market in a larger investigation into the safety of the medicines supply chain and presence of counterfeits. See *Cardinal Health Gets Subpoena in NY Probe*, REUTERS, Apr. 8, 2005, available at <http://www.foxnews.com/story/0,2933,152867,00.html>. Other wholesalers have been subject to investigations associated with illegally imported and fake drugs. See, e.g., *Arons v. Rite Aid Corporation*, No. BER-L4641-03, 2005 WL 975462 (N.J. Super. Ct. Law Div. Mar 23, 2005) (allowing plaintiffs to pursue individual claims against wholesaler and retailer who distributed fake Lipitor); *Government Files Motion to Intervene in Drug Wholesaler’s Lawsuit*, ASSOCIATED PRESS, Apr. 7, 2005, available at <http://www.contracostatimes.com/mld/cctimes/11334350.htm> (describing federal government motion to intervene in lawsuit against Kansas City wholesaler for its role in selling fake Lipitor). For an overview of the complexities of the gray market and its impact upon counterfeit drug distribution and sale, see generally KATHERINE EBAN, *A TRUE STORY OF COPS, COUNTERFEITERS, AND THE CONTAMINATION OF AMERICA’S DRUG SUPPLY* (2006).

⁷³ See Joel B. Finkelstein, *Drug Reimportation Situation is Shifting as Canada Could Cut Availability*, AMERICAN MED. NEWS, January 24, 2005. Note that counterfeiters are also entering into the medical device market, including surgical supplies. See Bob LaMendola *Firm Pleads Guilty in*

Physicians and nurses have little index of suspicion that a fake drug may be the cause of therapeutic failure,⁷⁴ generally attributing poor clinical outcomes to human variation.⁷⁵ Similarly, patients, their physicians, and their families may not know that they have been harmed by a fake drug, akin to patients dying without knowing they had a treatable illness.⁷⁶ Patients may also be frail, elderly, and/or very ill, further limiting suspicion. Providers rarely ask where drugs were purchased, and even in the unlikely event that they do, patients may be reluctant to disclose that medicines were bought over the Internet or from a foreign country.⁷⁷ Further, medication packaging is often thrown away. The material is also metabolized by the patient's body once taken and there are few lab tests normally available to detect the thousands of drugs that patients could be taking, hence drug levels are not easily obtained.⁷⁸ Consequently, no one suspects, no one tells, and any evidence is discarded or digested.⁷⁹ This situation makes it tremendously difficult to investigate

Sale of Potentially Tainted Product; A Hollywood-Area Company May be Hit With a \$10,000 Fine, SUN-SENTINEL (Florida), Apr. 28, 2005, at 3B (describing company who purchased fake surgical mesh overseas and then resold to a distributor as one of the first cases of counterfeit medical devices in the country). See generally Liang, *supra* note 48 (reviewing challenges of counterfeit drug detection).

⁷⁴ A case from China illustrates this tragically well. A father of a six year old girl died after receiving a fake hepatitis A vaccine; physicians repeatedly assured him 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, June 29, 2005, available at http://www.fra.org/english/news/social/2005/06/29/china_vaccinations.

⁷⁵ For example, in one counterfeit drug case, only 10% of the fake drug was ever recovered; hence 90% of the counterfeit drug may have gone undetected to 25,000 cancer and HIV patients. See Flaherty & Gaul, *supra* note 68, at A01. Further, in some cases, the provider may believe that 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 levels, so that any therapeutic, or lack of a therapeutic effect is not noticed. As well, the placebo effect may result in clinical action, even though there is no active ingredient in the drug. See Marv Shepard, *Drug Quality, Safety Issues and Threats of Drug Importation*, 36 CAL. W. INT'L L.J. 77 (2005).

⁷⁶ See, e.g., Joel S. Gross et al., *Autopsy Study of the Elderly Institutionalized Patient: Review of 234 Autopsies*, 148 ARCHIVES INT. MED. 173, 173 (1988) (describing findings that treatable illnesses are underdiagnosed); B. Szende et al., *Accuracy of Admission and Clinical Diagnosis of Tumours as Revealed by 2000 autopsies*, 32A(7) EUR. J. CANCER 1102, 1102 (1996) (describing diagnostic error rate in tumor related deaths verified by autopsy).

⁷⁷ This may be due to embarrassment or stigma associated with a particular disease state or frustration with access to the care desired. See Jim Thomson, Chief Executive, Centre for Mental Health, *Stigma? What Stigma?* (Sep. 6, 2005) (edited transcript available at http://www.ehiprimarycare.com/comment_and_analysis/index.cfm?ID=100).

⁷⁸ Note also that if the drug is a suspected fake, first, drug levels to test for the legitimate drug may not be available; and second, if attempting to determine if a fake material was used, one has to know what to test for—a daunting task with the plethora of substances used to create counterfeits.

⁷⁹ Even well known cases where information and the fake materials are available present challenges to any investigation and prosecution. Governments may also attempt to suppress information about counterfeit drugs, including through false certification of these drugs, which also creates significant barriers to detection. See Cockburn et al., *supra* note 14 (noting that often broad information about detection and scope of counterfeits is not provided because of fear of the negative affects this will have on legitimate sales). Further, physicians and government officials may actually be compromised and be part of the illegal activity. See *12 Doctors Involved in Spreading of Fake Drugs*, SUN STAR (PHILIPPINES), August 21, 2005, available at <http://www.sunstar.com.ph/static/pan/2005/08/21/news/12.doctors.involved.in.spreading.of.fake.drugs.health.office.html>.

Another related issue is that physicians have little tendency to discuss issues of medication costs with their patients, which avoids a substantive discussion of where to obtain legitimate drugs for the best price. See G.C. Alexander et al., *Physician Strategies to Reduce Patients' Out-of-Pocket Prescription Costs*, 165 ARCHIVES INT. MED. 633 (2005). There are, however, well-defined means by which physicians and others can educate patients regarding lower prices for drugs. See, e.g., Bryan A.

forensically where, how, and what occurred in a circumstance that may implicate fake medicines; such frustrations are stymieing investigations into recent counterfeit drug deaths in Canada.⁸⁰

Detection is also problematic for another reason: the quality of the packaging and counterfeit product. Often, the fake product looks identical to the actual medicine in form and in substance. In testimony for the Senate Health, Education, Labor, and Pensions committee, Graham Satchwell, a former detective superintendent and former Association of Chief Police Officers' spokesperson on counterfeiting, noted that:

[C]ounterfeit 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 recogni[z]e them when they and if 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.⁸¹

Hence, to detect counterfeit medicines in a clinical culture of limited suspicion and diagnostic uncertainty and a world of high quality fakes is a challenge that is virtually insurmountable. This situation truly makes counterfeit drug production and sale the perfect crime.

III. IMPORTATION: FROM GRAY TO BLACK

A. INTERNATIONAL EXPERIENCE

Although counterfeit/gray market problems are not well known in the United States,⁸² they are throughout the rest of the world.⁸³ International drug counterfeiting

Liang & Stephen H. Carson, *A Physician's Guide to Helping Patients Obtain Medication Savings*, SAN DIEGO PHYSICIAN, May 2005, at 23; Partnership for Safe Medicines, Safe Savings Brochure, SafeMedicines.org, <http://www.safemedicines.org/resources/resources/safesavings.pdf>; Partnership for Prescription Assistance, <http://www.pparx.org> (last visited Apr. 18, 2006) (describing the Partnership for Prescription Assistance as a program to join various players in the health care industry "to help qualifying patients who lack prescription coverage get the medicines they need through the public or private program that's right for them").

⁸⁰ See Luma Muhtadie, *Fake-Drug Case: Huge Forensic Challenges*, HAMILTON SPECTATOR (Ontario), July 16, 2005, at A01 (describing the unique challenges facing investigations into seven deaths associated with suspected counterfeit drugs).

⁸¹ *Drug Importation - Top European Security Expert Warns US Senate Panel on Risks*, MEDICAL NEWS TODAY, Apr. 20, 2005, available at <http://www.medicalnewstoday.com/medicalnews.php?newsid=23168>

⁸² "When people [in the US] 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." Oldenburg, *supra* note 20 (quoting Darren Pogoda, Staff Attorney, International Anti-Counterfeiting Coalition). Note, however, that US citizens may be putting themselves at risk by traveling to countries that have a high level of counterfeits. This becomes more of a risk as increased numbers of Americans travel to countries such as India for medical care. See, e.g., Ramola Talwar

difficulties are due in part to problems with parallel trade, i.e., international drug importation in Europe and other countries around the world.⁸⁴ Through parallel trade, drugs may pass through many different countries and scrupulous and unscrupulous sellers' hands before ending up in a pharmacy. The incentive to engage in this practice is attributable in part to differences in medicine pricing amongst European countries,⁸⁵ and is permitted in the EU under Article 28 of the European Commission Treaty for the Free Movement of Goods and Services within the Internal Market of the EU countries.⁸⁶ This principal of free movement mandates that no country within the EU may place legal, legislative, or other barriers preventing trade between members, nor may an owner of a trademark use its rights to prevent repackaging of the medicinal product if the repackaging will not adversely affect the original condition of the product.⁸⁷

Badam, *Westerners Seek Cheap Medical Care in Asia*, ASSOCIATED PRESS, Sept. 24, 2005, available at <http://www.freewmexican.com/news/32944.html> (describing increased number of western patients who seek medical attention overseas).

⁸³ See, e.g., Olenka Frenkiel, *One Woman's War with Fake Drugs*, BBC NEWS, July 12, 2005, available at http://news.bbc.co.uk/1/hi/programmes/this_world/4656627.stm (describing Nigeria's Dr. Dora Akunyili, the director of Nigeria's National Agency for Drug and Food Administration, whose sister died from fake insulin and whose country is filled with fake and sub-standard medicines that have killed adult and pediatric patients while noting the UK and US are not immune); *Huge Amount of Fake Pills Seized*, BULGARIAN NEWS NETWORK, August 5, 2005 (describing anti-organized crime police unit seizing 200,000 fake anti-headache pills); Mark Henderson, *It Would be Healthier for all of Us if Drug Companies Sounded Alerts on Counterfeits*, TIMES (London), Mar. 19, 2005, at 5 (describing conviction of counterfeiter who was found with over £6 million worth of fake medicines and a laboratory capable of producing half a million pills per day); Wandera Ojanji, *Weak Medicine: Ever Wondered why Sometimes You Take a Drug but Your Condition Worsens Instead of Improving? Chances Are You Are on a Counterfeit Drug*, STANDARD (Kenya), August 17, 2005, available at <http://www.eastandard.net/archives/cl/mags/executives/articles.php?articleid=27417&date=17/08/2005> (reporting over 50% of all medicines in Kenyan market are counterfeits); Erick Wamanji, *The \$10 Billion Fake Drugs Rip-Off*, ALL AFRICA, August 24, 2005, (describing "almost one out of every three people buying drugs from private pharmacies—even Government hospitals—are walking away with no more than plain water or chalk"). See also *infra* notes 84-105 and accompanying text (describing some European issues with counterfeit drugs). See generally Liang, *supra* note 48 (reviewing importation issues of parallel trade).

⁸⁴ Patricia Barry, *States Defy FDA on Drug Importation*, AARP BULLETIN, Oct. 2004, available at http://www.aarp.org/bulletin/prescription/Articles/a2004-10-08-fda_importation.html.

⁸⁵ *Global Forum on Pharmaceutical Anticounterfeiting Calls for Increased Corporate Responsibility and a Framework Convention*, EMEDIA WIRE, Mar. 21, 2005, at 1 available at <http://pdfserver.prweb.com/pdfdownload/219649/pr.pdf> (describing Second Global Forum on Pharmaceutical Counterfeiting, Paris, France, and noting the existence of "hugely divergent prices ... which in turn allows counterfeit products to be introduced"). Switzerland has been subject to at least two major cases of counterfeit drug trafficking in the last three years, and has convened a Council of Europe meeting on the topic sponsored by the Swiss Agency for Therapeutic Products (Swissmedic). See Matthew Allen, *Switzerland Joins Fight Against Fake Drugs*, SWISSINFO, Sept. 20, 2005, available at <http://www.nzz.ch/2005/09/20/eng/article6099293.html>

Note also that Europe has had similar problems with foodstuffs, which represent very much the same dynamic. For example, both Switzerland and Northern 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*, SWISSINFO, May 23, 2005, available at <http://www.nzz.ch/2005/05/23/eng/article5799697.html>; *Illegal food import seizures rise*, BBC NEWS, May 25, 2005, available at http://news.bbc.co.uk/2/hi/uk_news/northern_ireland/4579099.stm.

⁸⁶ See COMMISSION OF THE EUROPEAN COMMUNITIES, COMMISSION COMMUNICATION ON PARALLEL IMPORTS OF PROPRIETARY MEDICINAL PRODUCTS FOR WHICH MARKETING AUTHORIZATIONS HAVE ALREADY BEEN GRANTED (Dec. 30, 2003), http://europa.eu.int/eurlex/en/com/cnc/2003/com2003_0839en01.pdf.

⁸⁷ See *id.* at 12 ("It follows that the proprietor of the trade mark may not use his trade mark right in order to prevent repackaging when ... the repackaging cannot adversely affect the original condition of the product.").

There have been significant issues of counterfeits in Europe both domestically and across international lines relating to parallel trade.⁸⁸ Unfortunately, examples abound. The UK recently uncovered one of the largest counterfeiting operations ever discovered, which was churning out 500,000 tablets of counterfeit drugs *daily*, and which disseminated those products through parallel trade means across Europe.⁸⁹ It is interesting to note that in the UK, like the US and Latin America, penalties are light.⁹⁰ Allen Valentine, the mastermind of the UK counterfeit ring, who had been convicted on 14 previous occasions on charges of medication fraud, only received 5.5 years imprisonment—and the sentence was due to his copyright infringement, *not* his threat to public health.⁹¹ He is eligible for release in two years.⁹² This case follows several recalls and previous UK counterfeit discoveries⁹³ with attendant light

⁸⁸ In response to the growing issue of counterfeits, the Heads of Medicines Agency (HMA) has formalized a working group of European Risk Management Strategy to address pharmacovigilance and concern over counterfeit medicines. *See EU agencies to take action on safety and counterfeiting*, SCRIP PHARMACEUTICAL NEWS, July 19, 2005. Further, Maud de Boer-Buquicchio, Deputy Secretary of the Council of Europe in her opening speech to the Council of Europe seminar, *Counteract the Counterfeiters!* noted:

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 lifestyle medicines as well as essential medicines like antibiotics and insulin.
- Several indicators suggest that organised crime has found a currently lucrative and nearly safe business of counterfeiting medicines to generate resources for other criminal activities. Organised 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 recognised central reference point in Europe entrusted with 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.

Maud de Boer-Buquicchio, Deputy Secretary General of the Council of Europe, Limiting the Risks of Counterfeit Medicines to Public Health in Europe by Adequate Measures and Mechanisms (Sep. 21-23, 2005) (transcript available at http://www.coe.int/T/E/Com/press/News/2005/20050921_disc_sga.asp>http://www.coe.int/T/E/Com/press/News/2005/20050921_disc_sga.asp).

⁸⁹ Sam Lister, *The £6m Secret Factory That Churned out Thousands of Fake Viagra Tablets*, TIMES (LONDON), Nov. 27, 2004, at 9.

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *Id.*

⁹³ Counterfeit Zantac from Greece was detected in the UK in 1994. *See* GRAHAM SATCHWELL, A SICK BUSINESS 49 (The Stockholm Network, 2004). Counterfeit Cialis and Reductil were detected in August and September 2004, respectively. *See* Department of Health, Medicines and Healthcare Products Regulatory Agency, *Drug Alert Class 2 Medicines Recall (Action Within 48 Hours): Cialis 20 mg Tablets – Counterfeit Product* (August 23, 2004), <http://www.mhra.gov.uk/home/groups/is-md/documents/drugalert/con1002584.pdf> (UK); DEP'T. OF

penalties for its perpetrators.⁹⁴ More recent counterfeits have also been discovered, resulting in calls for scrutiny of the current regulatory safety structure.⁹⁵

Investigative efforts have outlined the significant issues facing Europe:

[D]rug 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 marketed, bought and sold there by wholesalers and then moved yet again to more expensive markets. ...

... Americans would be wise to consider the example of [the] United Kingdom as it 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.⁹⁶

Other European countries have also faced the problem of counterfeits. Wholesalers in Europe have been duped into introducing counterfeits into the

HEALTH, MEDICINES & HEALTHCARE PRODUCTS REGULATORY AGENCY, DRUG ALERT CLASS 2 MEDICINES RECALL (ACTION WITHIN 48 HOURS): REDUCTIL 15 MG CAPSULES (SIBUTRAMINE) PL 0037/0327 – COUNTERFEIT PRODUCT (Sept. 2, 2004), <http://www.mhra.gov.uk/home/groups/is-md/documents/drugalert/con1002582.pdf> (UK).

⁹⁴ An individual found selling £440,000 worth of counterfeit Viagra in the UK was sentenced to 150 hours of community service and £1,250 in costs by Isleworth Crown Court. See *Viagra Faker Sentenced*, CHEMIST & DRUGGIST (UK), July 2, 2005, available at 2005 WLNR 10561397.

⁹⁵ Fake Lipitor has been found in the UK salted with real Lipitor. See DEP'T. OF HEALTH, MEDICINES AND HEALTHCARE PRODUCTS REG. AGENCY, DRUG ALERT CLASS 2 MEDICINES RECALL (ACTION WITHIN 48 HOURS): LIPITOR TABLETS 20 MG, ATORVASTATIN (AS CALCIUM TRIHYDRATE), PL 16051/0002 (July 28, 2005), <http://www.mhra.gov.uk/home/groups/is-md/documents/drugalert/con2018023.pdf>; Sam Lister, *Heart Pills Taken by Millions Recalled as Fakes are Found*, TIMES (UK), July 28, 2005, at 2 (reporting statements by Nimo Ahmed, head of intelligence at the Medicines and Healthcare products Regulatory Agency, indicating that the discovery of the drugs which came from outside of the EU showed that counterfeit medicines could get into any supply chain, even the UK's, which is one of the most difficult to penetrate). See also Celia Hall, *Internet Fuels Boom in Counterfeit Drugs*, DAILY TELEGRAPH (UK), Aug. 16, 2005, at 9 ("In the past year three counterfeit medicines have reached the public in Britain, having penetrated legitimate pharmacy outlets. They were fake Cialis, a drug for impotence, fake Reductil, a slimming drug, and fake Lipitor, a drug to lower cholesterol."); Catherine Humble, *Inside the Fake Viagra Factory*, SUNDAY TELEGRAPH (UK), Aug. 22, 2005, at 11 (describing another discovery of fake Viagra and the unsanitary conditions for production of counterfeit medicines) Andrew Jack, *Probe Ordered After Fake Drugs Find*, FINANCIAL TIMES (UK), Aug. 16, 2005, at 3 ("The medicines regulator has launched fresh inquiries into pharmaceutical distributors after discovering a second batch of counterfeit anti-cholesterol drugs in two weeks. The agency said it had found new copies of Pfizer's best-selling drug Lipitor, which had been packaged for the UK market."); Andrew Jack, *Tackling Counterfeiters Who Make Pills in Cement Mixers*, FINANCIAL TIMES (UK), Aug. 16, 2005, at 3 ("The World Health Organisation 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.").

⁹⁶ See *Drug Importation -- Top European Security Expert Warns Senate Panel on Risks*, Apr. 22, 2005, http://www.procosolutions.com/html/drug_importation.html. (quoting former detective superintendent and Association of Chief of Police Officers' spokesperson Graham Satchwell on counterfeiting). Note also that there are other risks of using Europe as a source of medicines: foreign drugs may have the same name as US drugs but contain different ingredients due to differences in naming across borders. See Marilyn Chase, *Buying the Wrong Medicine Overseas*, WALL. ST. J., August 16, 2005, at D1.

legitimate supply chain, such as the case in The Netherlands in 2004.⁹⁷ In Italy, a licensed medicines dealer was found to be distributing counterfeit gastrointestinal drugs.⁹⁸ In France, custom's agents seized 542,000 fake drugs in 2003.⁹⁹ In Spain, authorities raided six laboratories producing counterfeit steroids, hormones, and cancer drugs.¹⁰⁰ The operation was capable of producing 20,000 fake doses per hour; 30 million doses and 10 tons of high quality tablets were found, with vials, capsules, tablets, and injectables all represented.¹⁰¹ These fake products were confirmed to have been sold through parallel trade in Italy, France, and Portugal, and more broadly through the Internet.¹⁰²

Hence, it is no surprise that patients' groups such as the UK Patients' Association have voiced their concerns about the dangers of counterfeits and parallel trade in Europe: "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."¹⁰³ "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."¹⁰⁴ Reflecting these concerns, the European pharmaceutical supply situation has been described as follows:

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.¹⁰⁵

⁹⁷ See Julian Mount, *Safer Pharmaceutical Distribution in Europe*, in PROGRESSIONS 2005: THE ERNST & YOUNG GLOBAL PHARMACEUTICAL REPORT 15 (2004).

⁹⁸ See SATCHWELL, *supra* note 93.

⁹⁹ See PARTNERSHIP FOR SAFE MEDICINES, COUNTERFEIT DRUGS IN EUROPE FACT SHEET (2005), <http://www.safemedicines.org/resources/europe.pdf> (citing Claude Foquet, *Increase in counterfeit goods seized in France*, LES ECHOS, Mar. 22, 2005).

¹⁰⁰ See Partnership for Safe Medicines, *supra* note 99 (citing Pharmaceutical Security Institute Memorandum, June 24, 2005).

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ See Epilepsy Action – News Archive, *Conference Spotlights Medication Importing and Counterfeiting*, Sept. 14, 2004, <http://www.epilepsy.org.uk/news/archive/20040914.html>.

¹⁰⁴ *Counterfeit Lipitor: Pfizer Urges UK Govt, EU Action Including a Repackaging Ban*, PHARMA MARKETLETTER (UK), August 2, 2005, available at 2005 WLNR 12969838 (quoting Jim Thomson of the UK Centre for Mental Health).

¹⁰⁵ See PARALLEL TRADE IN MEDICINES: RESULTS OF A SOCIAL MARKET FOUNDATION DISCUSSION SEMINAR 19 (Niall Maclean ed., The Stockholm Network 2004). See also Severin Carrell, *IOS Investigation: On the Trail of the World-Wide Web of Fake Lifestyle Drugs*, INDEPENDENT ON SUNDAY (UK), Jan. 18, 2004, at 8 ("Poland, Bulgaria and Turkey . . . [A]re all poised to join the European Union, and are havens for illegal drugs factories and smugglers. Their long frontiers border countries such as Russia that are notorious for the ready availability of fake drugs."); Severin Carrell, *Over 50 Per Cent of Viagra Sold Online is Fake*, INDEPENDENT ON SUNDAY (UK), October 3, 2004, at 14 ("Paypill.com, which claimed to be a London-based business, was exposed in January for selling counterfeit Viagra. It promised it would stop selling the drug. But

Indeed, the problem in a nutshell is very much like issues associated with safe sex: You may trust the person you are with right now, but do you trust every person that person has had sex with to have used appropriate protections? Do you trust those others to have ensured that all the individuals they have had sex with to have ensured their partners had appropriate protection? You may trust the representative who is selling you drugs across the counter, but do you trust all the other persons who have handled the medicine? Do you trust all those others to have stored the drugs in appropriate conditions, to have ensured security of the drugs, and to have verified their authenticity? Because importation may extend the gray market outside our closed system to worldwide suppliers, the counterfeit drug problem the world experiences may become our own. So through importation, we may move from the gray market to the black: from getting drugs from legitimate secondary wholesalers with its accompanying weaknesses to the international black market and its tremendous risks, including maiming, worsening illness, and death.

B. POLITY ISSUES

The question also arises as to just who the polity is comfortable with in terms of importation trading partners. Surveys have shown that US consumers favor importation from Canada—although certainly not uniformly: one large survey showed that 69% favored some form of importation of prescription drugs from Canada.¹⁰⁶ But most consumers were opposed to importation from other countries, such as those within the European Union and Asia.¹⁰⁷ Further, senior citizens and women, the “health care gatekeepers,” were most opposed to importation.¹⁰⁸

Yet surveys like this one beg the question, regardless of their results: do consumers know that importation from “Western” countries like Canada, Ireland, and the UK, include medications that originated from eastern bloc European countries or Asia?¹⁰⁹ It is unlikely that the vagaries of the drug distribution and importation markets domestically and internationally are everyday discussion points for US consumers. Indeed, Canada itself currently imports drugs from 80 countries, including countries with high levels of suspect drugs.¹¹⁰ Hence, in the context of the evidence to suggest that there is at least some resistance to broad importation, and

after relocating from south-east France to Spain, Paypill again began selling tablets . . . Paypill reacted by closing down its website late on Friday – but continued to insist it bought its tablets from the same wholesalers that supply the NHS. It claimed: ‘We have never, ever knowingly sold counterfeit drugs.’”)

¹⁰⁶ See *Americans Don't Favor Drug Imports from Non-Canadian Countries; Details of Drug Import Bill Meet Stiff Resistance in All Quarters, with Older Americans, Women Most Strongly Opposed*, U.S. NEWSWIRE, Mar. 8, 2005, <http://releases.usnewswire.com/GetRelease.asp?id=44001>.

¹⁰⁷ Interestingly, there was more support for importation from Greece, Portugal, and Spain than from the European Union generally. See *id.*

¹⁰⁸ See *id.* Other patient groups are also opposed to importation from Canada. See, e.g., William P. Bro, *Canadian Drugs No Miracle Cure*, SEATTLE POST-INTELLIGENCER, February 8, 2005, at B7 (describing the dangers of importation and the limitations on treatment development from the perspective of a cancer survivor).

¹⁰⁹ Here again, surveys find disparate results. AARP claims wide support for importation under the Dorgan bill. See *supra* note 106. See also *infra* note 156 and accompanying text. However, another study indicates that seniors oppose importation strongly after being given details about the legislation. See *Study: Seniors, AARP Members Have Serious Concerns with Rx Importation; Study Finds AARP Not Representing Seniors on Drug Importation Issue*, U.S. NEWSWIRE, July 28, 2005, <http://releases.usnewswire.com/GetRelease.asp?id=51045>.

¹¹⁰ Marv Shepherd, *What if Canada Says 'No' to U.S. on Drug Imports?* USA TODAY, Dec. 29, 2004, at 13A (including information that Canada imports drugs from countries such as Ecuador, Singapore, India, Hungary, and China).

the reasonable likelihood that Americans do not, in general, realize that importation from Canada and “acceptable” countries does not exclude less desirable sources, the debate on importation by policymakers should encompass these realities and educate the polity when considering costs and implementation issues of this policy alternative.¹¹¹

This debate should focus on safety as the key issue. Although state governors have issued executive orders and state legislatures have in fact passed bills allowing for importation,¹¹² pharmacists and legislators have voiced their concerns, as these programs expand their importation sources to countries with demonstrated safety issues.¹¹³ For example, Senator Leticia Van De Putte, a Texas Democrat and pharmacist, warned against allowing Canadian Internet purchases of drugs by citizens in her state: “It is a risk Texas should not be taking ... Do you really want to take a chance with your mom’s high blood pressure or your son’s seizure disorder?”¹¹⁴ Indeed, Canada has not been immune to counterfeits and deaths associated with such drugs; coroners, the Royal Canadian Mounted Police, and the Ontario College of Pharmacists are currently investigating several deaths associated

¹¹¹ Andrew Johnson, *Support for Drug Imports Varies: Medicines from Canada Favored*, WASH. TIMES, Mar. 9, 2005, at C8. (“I think a part of what surprised us looking at the various bills that are being debated on [Capitol] Hill go beyond Canada,” said Steven Gibson, vice president of government relations and public affairs for the Amyotrophic Lateral Sclerosis (ALS) Association. “That really hasn’t been coming out through the media or the grass roots.”).

¹¹² For example, Illinois created the I-Save-Rx program, which is probably one of the most well known programs. See 27 ILL. REG. 10122 (July 7, 2003). Note that some Governors have suggested circumventing federal prohibitions through contracting with sovereign Native American nations, although this, too, is considered illegal. See Amy J. Maggs, *Reimportation: Panacea or Prescription for Disaster*, 18 BENEFITS L. J. 112, at n. 21 and accompanying text (2005).

¹¹³ It is interesting to note that state programs continue to expand the countries through which it will allow purchases, even countries that have experienced problems with counterfeiting and the polity appears resistant to allow. See, e.g. Pawlenty to Announce Prescription Plan Including Europe, WCCO ASSOCIATED PRESS, Mar. 15, 2005, available at http://wcco.com/consumer/local_story_074143827.html (describing Minnesota Governor Pawlenty’s announcement to extend drug importation program to multiple European outlets); *Pharmacists React to CanRx Exploring Importation of Drugs from India: Bloomberg Article Reveals Canadian Internet Pharmacy is Considering Use of Drugs from Country Associated with Counterfeits*, PRNEWswire, Mar. 16, 2005 (describing CanRx, supplier to the Illinois I-Save-Rx drug importation program that also supplies drugs to Missouri, Wisconsin, Kansas, and Vermont, which “has joined other Canadian Internet pharmacies in finding sources of drugs from partners in the U.K., Continental Europe, Israel, Australia, and India.” India, according to a study by the Temple University Center for Pharmaceutical Health Services Research, is the worldwide leader in the production of counterfeit drugs with as much as 35 percent of the world’s counterfeiting originating from that country.”).

In addition, state representatives in some cases have not actually secured permission of the country’s government, nor addressed significant legal issues. For example, the I-Save-Rx program announced it had expanded its scope of pharmacies in the program to Australia. However, program officials did not speak to the Australian government nor doctor groups; exporting Australian domestic drugs subsidized by the government is illegal, and physicians must write prescriptions for Australian pharmacies to be able to dispense medicines—something they will likely resist because they do not see the patient. See Mark Coultan, *Bitter Pill Poppers Cut Costs*, SYDNEY MORNING HERALD (AU), July 20, 2005, available at <http://www.smh.com.au/news/national/bitter-pill-poppers-cut-costs/2005/07/19/1121538975659.html?one>.

¹¹⁴ See *Canadian and U.S. Pharmacists Meet in Texas to Warn Against Internet Drug Sales*, CAN. PRESS, Apr. 7, 2005. Note that both Texas pharmacists and Canadian pharmacists were vocal about their resistance to the state importation bill. See *Texas and Canadian Pharmacists, State Legislator, Align to Fight Importation of Internet Drugs*, PR NEWswire, Apr. 5, 2005. The FDA considers such Canadian purchasing programs in violation of federal law. The Texas Board of Pharmacy will not act upon the legislation until it receives an advisory opinion from the state Attorney General. See *Canada Prescription Drug Law on Hold*, AP ALERT – TEXAS, Aug. 31, 2005.

with imported counterfeit cardiac drugs sold from a pharmacy there and have brought charges against another pharmacist for selling fake drugs.¹¹⁵

It should also be noted that medicines not earmarked for domestic consumption are not subject to that country's safety laws.¹¹⁶ Consequently, state programs purchasing drugs from Canada and elsewhere that are simply earmarked for export to the US and not to be consumed by Canadian citizens are not subject to Health Canada or the domestic country's regulatory requirements on safety.¹¹⁷ Therefore, drugs from India and China,¹¹⁸ for example, if only passing through Canada en route to US citizens are not subject to Health Canada safety rules. Hence it is impossible to determine whether the drugs US consumers are buying are legitimate and safe or not. And in such as setting, "the door to abuse is open," resulting in, for example, Canadian pharmacies selling unapproved drugs to the US from non-Canadian sources such as Mexico.¹¹⁹

Further, as a matter of what might be termed "pharmaceutical imperialism," Canada may simply not wish to be "America's drugstore."¹²⁰ Canada has a population one-tenth the size of the US; hence it is impossible for it to serve US needs for medicines as well as its own.¹²¹ In response to fears of US demand limiting Canadian domestic supply, patient groups and pharmacists in Canada are calling for regulations to stop export of prescription drugs and greater oversight of Canadian

¹¹⁵ See Testimony of John Theriault, Before the U.S. Dep't. of Health & Human Services Importation Task Force (Apr. 5, 2004), available at <http://www.hhs.gov/importtaskforce/session2/transcript.html> [hereinafter Theriault]; *Coroner Probes Five Deaths in Pharmacy Investigation*, CBC NEWS, June 23, 2005, <http://toronto.cbc.ca/regional/servlet/View?filename=to-pharmacy20050623>; Muhtadie, *supra* note 80; *Pharmacist Charged in Counterfeit Drug Case*, GLOBE & MAIL, Sept. 10, 2005, at A15 (describing criminal charge against a pharmacist in Canada for dispensing counterfeit drugs to patients that has resulted in five patient deaths). See also *Ontario Pharmacist Charged After RMCP Seize Bootleg Viagra from India*, BROADCAST NEWS, Sept. 27, 2005 (describing sale of fake Viagra in Canada and raising concerns about safety of Canadian drug supply).

¹¹⁶ See TASK FORCE, *supra* note 10, at 60-61 ("Health Canada does not assure that products being sold to U.S. citizens are safe, effective, and of high quality, and does not intend to do so in the near future.").

¹¹⁷ See *Id.*; World Health Organization, *supra* note 16; Christine Clark, *British Pharmaceutical Conference 2003: Counterfeiting*, 271 PHARMACEUTICAL J. 453, 454 (2003); Bill Kirven, *Drugs from Canada are No Bargain*, ROCKY MTN. NEWS, January 17, 2005, at 44A ("Canada isn't a willing player in the reimportation game. 'The government of Canada has never stated that it would be responsible for the safety and quality of prescription drugs exported from Canada into the United States,' Canadian Health Minister Ujjal Dosanjh said in November."). See also Shepherd, *supra* note 110; *Maine and Canadian Pharmacists Join Hands to Fight Importation Programs That Threaten Patient Safety*, PR NEWswire, Mar. 29, 2005 ("Drugs that enter Canada to be exported to customers in the United States are not subject to review or regulation by Health Canada. There is no guarantee that imported drugs are safe.").

¹¹⁸ India and China produce a large portion of the world's counterfeit drugs. Other countries have had long experience with these countries' fakes and have banned many drugs from these countries. See, e.g., Joydeep Ray, *Pharma Firms Face Fake-Drugs Charge in Nigeria*, BUS. STANDARD, Apr. 8, 2005, at 11.; *Nigeria Blacklists 11 Indian Drug Companies*, BUS. LINE, Apr. 6, 2005 (reporting that Nigeria has banned pharmaceutical imports from companies based in India, China, and Pakistan).

¹¹⁹ Shepherd, *supra* note 110. Note that World Health Organization figures indicate that 40 percent of medicines from Mexico are fake. See, e.g., *Counterfeit Drugs Deemed Threat in Europe*, AP ONLINE, Sept. 22, 2005.

¹²⁰ Indeed, as Canadian Minister of Health Ujjal Dosanjh has stated, not only may it not wish to be America's drugstore, it physically cannot be. See The Honourable Ujjal Dosanjh, Can. Minister of Health, *Health in a Global Society: A Canadian Perspective*, Address at Harvard Medical School, Cambridge (Nov. 10, 2004) (transcript available at http://www.hc-sc.gc.ca/ahc-asc/minist/health-sante/speeches-discours/2004_11_10_e.html).

¹²¹ See Shepherd, *supra* note 110.

Internet pharmacies—of which 95% of their business is mail order from the US.¹²² These groups fear that unfettered sales of Canadian supplies may result in shortages and increased prices for them, a fear that has been supported by economic analysis.¹²³ Canadian Health Minister Ujjal Dosanjh apparently agrees and has limited bulk exports of prescription drugs as part of a program to regulate Canadian Internet pharmacists selling to the US.¹²⁴

C. DORGAN BILL

The major drug importation bill currently under consideration in Congress is S.334, the Pharmaceutical Market Access and Drug Safety Act of 2005, introduced by Sen. Byron Dorgan.¹²⁵ This bill would amend the Food, Drug, and Cosmetic Act¹²⁶ to allow commercial and personal importation of prescription drugs.¹²⁷

In general, S.334 would require the Secretary of the Department of Health and Human Services to promulgate regulations that would allow importation through registered exporters and registered importers from a broad array of countries.¹²⁸ The

¹²² See *id.* See also *Pharmacists Fault Maine Drug Reimportation Plan*, MAINETODAY.COM, Mar. 31, 2005, <http://business.mainetoday.com/news/050331.drugs.shtml> (“How is a country with 30 million citizens going to be able to supply the prescription needs of a country with 280 million? Raiding Canada’s medicine cabinet will not solve health care problems in the U.S.,” quoting Marc Kealy, Ontario Pharmacists’ Association).

¹²³ See, e.g., Todd A. Rosenfield, Comment, *The Counterfeit Drug Invasion: How Drug Re-Importation Unjustifiably Poses a Threat to the Health of the U.S. Public*, 25 U. PA. J. INT’L ECON. L. 1047, 1067 (2004) (explaining that drug shortages, increased prices, and ironically, higher resultant prices to US consumers may result from importation). See also Christopher Conkey, *States’ Bid for Cheaper Medicine Sputters*, WALL ST. J., Feb. 14, 2005 (“Many Canadian pharmacies have had to buy supplies from fellow retailers at higher prices.”); Brian Ferguson, *Alice in Borderland: Why Canadians Cannot Afford to be Complacent About American Drug Re-Importation*, AIMS COMMENTARY 1 (Oct. 2004), available at <http://www.aims.ca/library/reimportation.pdf> (asserting that if drug importation is allowed in the US from Canada, US prices will not fall and Canadian prices will rise to US levels or supplies will be restricted resulting in shortages).

¹²⁴ See *Ban of Prescription Drug Imports in the Works*, GLOBE AND MAIL (Can.), June 27, 2005, available at <http://www.globetechnology.com/servlet/story/RTGAM.20050627.gtats27-2/BNStory/Technology>.

¹²⁵ S.334, 109th Cong. (1st Sess. 2005), available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_bills&docid=f:s334is.txt.pdf. (Co-sponsors include Sens. Snowe, Grassley, Kennedy, McCain, Stabenow, Chafee, Jeffords, Lott, Dayton, Clinton, Bingaman, Boxer, Conrad, Durbin, Feingold, Feinstein, Inouye, Johnson, Kohl, Leahy, Levin, Nelson, 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 has actually been federal law allowing for importation. In 2000, the Medicine Equity and Drug Safety Act was passed, which would allow drug importation in the effort to reduce medication prices. 21 U.S.C. § 284 (2000). However, then-Secretary of the Department of Health and Human Services, Donna Shalala, de-implemented the statute. 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”. 21 U.S.C. § 384(l)(1)(2000). 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 superseded 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. Pub. L. No. 108-173, 117 STAT. 206 (2003), No such certification has been made to date

The Pharmaceutical Market Access Act of 2003, H.R. 2427, 108th Cong. (2004), the Safe IMPORT Act of 2004, S. 2493, 108th Cong. (2004) and the Pharmaceutical Market Access and Drug Safety Act of 2004, S. 2328, 108th Cong. (2004) are recent, failed efforts to allow drug importation. The latter bill is virtually identical to the current S.334.

¹²⁶ 21 U.S.C. §§ 381-384 (2000).

¹²⁷ S. 334 at § 4. See generally Liang, *supra* note 48 (criticizing Dorgan Bill).

¹²⁸ *Id.*

bill would allow personal importation of drugs pending regulations regarding a commercial importation system.¹²⁹ The bill would also amend the Clayton Antitrust Act¹³⁰ and prohibit drug manufacturers from penalizing or acting to limit sales to foreign suppliers who move to participate in the commercial importation program.¹³¹ Further, the bill would overrule federal precedent that currently deems that foreign sale of a product does not exhaust the domestic patent and intellectual property protections so associated.¹³²

Although there is no doubt that the bill and its supporters are attempting to address the high costs of pharmaceuticals in this country, there are some significant safety issues implicated by its provisions.¹³³ First, the bill allows for personal and commercial importation of drugs not only from Canada; but also from Japan, Australia, New Zealand, Switzerland, as well as the EU.¹³⁴ Countries that may become suppliers under the bill may either receive or have significant importation and counterfeit problems themselves, particularly the EU.¹³⁵ Further, the list is not exclusive; additional countries may be added if that country has statutory or regulatory requirements or regulations that include a review of safety and efficacy, good manufacturing processes, adverse event alert mechanisms, and rules on labeling and promotion.¹³⁶ Many countries may fulfill these requirements in form while not implementing them substantively.¹³⁷

¹²⁹ *Id.*

¹³⁰ 15 U.S.C. §§ 12, 13, 14-19, 20, 21, 22-27 (2000).

¹³¹ S. 334, *supra* note 125, at § 4.

¹³² *See Jazz Photo Corp. v. Int'l Trade Comm.*, 264 F.3d 1094 (Fed. Cir. 2001), *cert denied*, 536 U.S. 950 (2002).

¹³³ Members of the Senate Health, Education, Labor, and Pensions Committee also had some concerns about safety 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 (“In a heated exchange with Snowe, Gregg pressed the issue of safety and grilled her on the changed 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.”). Other experts were also wary. 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 on Risk of Drug Importation; Urges Congress to Learn from Problems Faced by European Union*, PHARMALIVE, Apr. 19, 2005.

¹³⁴ *See* S. 334 at 9-10.

¹³⁵ *See supra* notes 67-87 and accompanying text (discussing EU and Canadian problems with counterfeit drugs). Countries that would immediately be allowed to provide imported drugs hence 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 UK. Some of these countries, *see id.*, have encountered significant problems with counterfeits. Indeed, testimony by John Theriault, Vice President for Global Security, Pfizer, Inc., before the Drug Importation Task Force noted that “With 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.” Theriault, *supra* note 115.

¹³⁶ *See* S. 334 at 10-11.

¹³⁷ For example, Russia may be a country that fulfills this provision, as may China and India—countries that have legitimate pharmaceutical industries, but also have significant counterfeit medicines production. *See, e.g., Moscow Police Bust Counterfeit Medicine Factory*, MOSCOW NEWS (Russia), July 12, 2005, available at <http://www.mosnews.com/news/2005/07/12/falsedrugs.shtml>

Indeed, even the FDA has had its own operations criticized regarding safety and public health, including the Vioxx withdrawal (which was initiated by Merck, the manufacturer, not ordered by the FDA), problems associated with antidepressant use in children,¹³⁸ as well as counterfeits.¹³⁹ Part of the reason for these results is that the FDA is chronically underfunded, leading to situations in which scarce resources must be stretched and policies prioritized for enforcement to the exclusion of others, even in the context of safety mandates and the good faith of those who work there.¹⁴⁰ If the current US system has significant issues of monitoring safety within its borders now, it would be difficult to envision a system where it would also be responsible for tight security and safety of pharmaceuticals domestically under a system of importation *and* adequately assess other countries' systems which may be, in practice, as empirically flawed if not more so in their regulatory activities and outcomes.

The limited funding also creates issues for the regulation of US importers and foreign exporters in the bill. For example, domestic importers and foreign exporters would be required to register with the Department of Health and Human Services.¹⁴¹ Part of this registration would include information on the places of business, locations of warehouses and other related facilities.¹⁴² As well, the bill would require information on the sources of the drugs to be imported, as well as a promise that the registrant will not import/export any drug that does not qualify under the bill.¹⁴³ The Secretary of the Department of Health and Human Services has 90 days to approve or disapprove the registration.¹⁴⁴ It would seem that certainly the FDA would not have the funds to verify the information associated with the registrants, and it is highly unlikely that each and every registrant's facility, domestically and internationally, as well as the sources of drugs for import/export, would be verified and inspected, particularly under the 90 day constraint. Hence, key aspects of the medicines covered by the program—who, which, and where, particularly on the foreign export entities' end—would not be subject to practical review.

In addition, other issues arise with respect to the sources of drugs. The bill would require that drugs obtained for US consumer use to have a pedigree statement showing the chain of custody.¹⁴⁵ However, considering the sophistication that drug

(describing Moscow police bust of counterfeit medications which were sold in Moscow, St. Petersburg, and other regions).

¹³⁸ See, e.g., Bryan A. Liang, *Flaws in the U.S. Drug Safety System*, S.D. UNION TRIBUNE, Nov. 29, 2004, at B7, available at http://www.signonsandiego.com/uniontrib/20041129/news_lz1e29liang.html

¹³⁹ See *Vioxx Concerns Spawn New FDA Drug Safety Board*, NEWS TARGET, Feb. 28, 2005, available at <http://www.newstarget.com/005048.html> (last visited Mar. 1, 2005).

¹⁴⁰ See, e.g., Arthur A. Levin, *Science Under Attack by the Bush Administration*, CENTER FOR MED. CONSUMERS (Nov. & Dec. 2002), http://www.medicalconsumers.org/pages/science_under_attack.html (“User fees also have provided Congress with cover for their historic underfunding of the FDA. The result is that the agency cannot adequately carry out many of the public protection duties that Congress has assigned it.”); Charles Marwick, *FDA Funding Problems Imperil Safety of Biological Products in the United States*, 279 JAMA 899 (1998); 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 . . .”).

¹⁴¹ See S. 334 at 12-13.

¹⁴² See *id.*

¹⁴³ See *id.* at 13-14.

¹⁴⁴ See *id.* at 18.

¹⁴⁵ “(3) The exporter or importer obtained the drug—(B) directly from an entity that, by contract with the exporter or importer—(i) provides to the exporter or importer a statement . . . that, for

counterfeiters have exhibited in making holograms, package inserts, and the drugs themselves,¹⁴⁶ it is highly unlikely that they would not be able to generate reasonable fake pedigree documentation.¹⁴⁷ As well, the issue of inspection and verification also once again makes it difficult to see how, in a world of limited resources, these pedigree papers would be effectively checked.

It should also be noted that there are no criminal sanctions associated with fake papers.¹⁴⁸ Instead, the bill relies on contractual agreements between the parties involved in the importation to ensure and police validity.¹⁴⁹ In other words, civil sanction by breach of contract would be the primary means for pedigree accountability. This would provide little if any disincentive to produce and pass off fake drugs. The bad faith producer is out of the country, and is not legitimate; hence, the potential for a civil suit for damages is unlikely to give it pause once it collects its ill-gotten gains through its sales—assuming the fake goods are ever detected in the first place.

The bill does provide that foreign exporters agree to subject themselves to inspections in order to participate in the importation program, which includes determination of pedigree.¹⁵⁰ The Secretary is empowered to assign “1 or more” employees to perform this inspection,¹⁵¹ and these inspections must occur not less than 12 times annually.¹⁵² It would appear that the FDA would be responsible for these activities, since it would receive fees from registrants participating in the program.¹⁵³ Although these goals are laudable, the resource issue arises again. Just how will each facility be inspected an average of once a month—facilities that can range from Australia to Japan to Austria to Latvia? How many inspectors will be needed? Recall that the FDA has only 16.9 inspectors for all of the international mail facilities in the US.¹⁵⁴ But through expansion of exporting entities to world-wide facilities, and broader sources than ever before, it is totally unreasonable to expect any agency or department to be able to substantively verify the quality and pedigree of all the hundreds to thousands of exporters that would participate under the terms of the bill.¹⁵⁵

Other impracticalities also accompany the bill’s importation process. The bill would require that notice be given “not less than 8 hours and not more than 5 days in

the chain of custody from the establishment, identifies each prior sale, purchase, or trade of the drug” *See id.* at 23.

¹⁴⁶ *See* On the Loose: Protect Yourself from Counterfeit Drugs, <http://www.fraud.org/fakedrugs/faq.htm> (last visited Apr. 18, 2006).

¹⁴⁷ *See* Robb Miller, *Tracking Papers Won’t Help*, USA TODAY, May 30, 2005 (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).

¹⁴⁸ *See* S. 334 at 24.

¹⁴⁹ *Id.* at 24.

¹⁵⁰ *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.

¹⁵¹ *See id.* at 26.

¹⁵² *See id.* at 27.

¹⁵³ *See id.* at 36,41.

¹⁵⁴ *See supra* note 35 and accompanying text.

¹⁵⁵ Note that the number of inspections of registered exporters in the first year would be a minimum of 600 (12 inspections a year with a minimum of 50); *see id.* at 92. For the second year, a minimum of 1200 (12 inspections a year with a minimum of 100); the number of importers would be even greater, with at least 1200 the first year (12 inspections a year with a minimum of 100), and at least 2400 the second year (12 inspections a year with a minimum of 200). *See* S. 334 at 93-94.

advance of the time of the importation of a shipment of qualifying drugs".¹⁵⁶ Information required would include:

- (A) the name and complete contact information of the person submitting the notice;
- (B) the name and complete contact information of the importer involved;
- (C) 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;
- (D) the identity of the manufacturer of the drug, including the identity of the establishment at which the drug was manufactured;
- (E) the country from which the drug is shipped;
- (F) the name and complete contact information for the shipper of the drug;
- (G) anticipated arrival information, including the port of arrival and crossing location within that port, and the date and time;
- (H) a summary of the chain of custody of the drug from the establishment in which the drug was manufactured to the importer;
- (I) 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
- (J) such other information as the Secretary may require by regulation.¹⁵⁷

This is a tremendous amount of information to process. A completely new infrastructure would need to be created just to collect and collate all of this information, even assuming all of it is true and relevant. Scarce resources would necessarily be allocated to this recordkeeping activity rather than reserved for direct safety-related efforts.

The bill does try to address the issue of financial resources for the program. In general, there will be a registration fee and inspection fee paid by importers¹⁵⁸ and exporters¹⁵⁹ to fund the importation program. Yet, this type of financial underwriting of government scrutiny by those to be scrutinized creates significant conflicts of interest. Indeed, such a process is akin to the tremendous conflicts surrounding pharmaceutical drug application user fees provided to the FDA, and the intense criticism of this practice by neutral bodies.¹⁶⁰ To have importers and exporters fund their own review process would make the entity performing that review completely dependent upon the industry that they are responsible for inspecting. Although, like the FDA, there are many who would act ethically and reasonably, also like the FDA, such a situation may subject the agency to Congressional budget cuts and conflict of interest charges. Indeed, the bill would allocate the funding raised by the importer/exporter user fee scheme to the FDA for regulatory activities under the bill.¹⁶¹ This approach, that has resulted in potential safety concerns in other

¹⁵⁶ See *id.* at 28-29.

¹⁵⁷ See *id.* at 29-30.

¹⁵⁸ See *id.* at 32.

¹⁵⁹ See *id.* at 37.

¹⁶⁰ See, e.g., Marcia Angell, *What Ails the FDA? Payola*, BOSTON GLOBE, Mar. 10, 2005; Phil B. Fontanarosa, et al., *Postmarketing Surveillance—Lack of Vigilance, Lack of Trust*, 292 JAMA 2647 (2004); Gary W. Lawson, Letter to the Editor, *FDA Dependence on Drug Industry*, 97 J. NAT'L MED. ASS'N 1039 (2005); Alexandra Marks, *How Drug-Approval Woes Crept up on FDA: Critics Charge Conflict of Interest in a System Where Pharmaceutical Giants Fund the Regulatory Process*, CHRISTIAN SCI. MONITOR, Nov. 26, 2004.

¹⁶¹ See S. 334 at 36. The Bureau of Customs and Border Protection would be an optional beneficiary of such fees. *Id.*

pharmaceutical contexts, has no place in the province of safety of the medicine supply.¹⁶²

Beyond policy concerns, there is also a significant issue of drug safety and efficacy with respect to qualifying drugs in the importation program. The bill would allow non-bioequivalent versions of drugs to be imported into the US.¹⁶³ Such non-bioequivalent forms generally include different excipients.¹⁶⁴ However, differing excipients represent risks associated with patient adverse reactions to medicines, a risk that has been known for some time.¹⁶⁵ Indeed, the FDA itself has indicated the need to be concerned about excipients as toxicants; known reactions to excipients include renal failure, osmotic diarrhea, hypersensitivity reactions, cardiotoxicity, and death.¹⁶⁶

Further, simply on the domestic level, drug forms that have been deemed bioequivalent by the FDA have created adverse drug therapeutic results.¹⁶⁷ But in the context of importation, the international definition of “bioequivalent” will be critical. Unfortunately, countries including those in the EU, as well as Latin America, do not have harmonized definitions of bioequivalent, or, as it is known in the EU, “essentially similar” medicines.¹⁶⁸ This will create significant conflicts as to the determination, and hence legal requirements, associated with imported bioequivalent versus non-bioequivalent drugs including those regarding labeling for warning purposes.¹⁶⁹ More importantly, substantive patient care and patient safety issues associated with the drug will arise. This situation may exacerbate investigations of the causes of adverse drug reactions if the drug is labeled bioequivalent when the excipients are not, the drug is not, or both.

¹⁶² See *supra* note 160 and accompanying text.

¹⁶³ See S. 334 at 61-63.

¹⁶⁴ Excipients are the non-therapeutic materials within the drug. See Thomas A. Wheatley, *What Are Excipients?*, in *EXCIPIENT TOXICITY AND SAFETY* (Myra L. Weinger & Lois A. Kotkoskie eds., 1999).

¹⁶⁵ See, e.g., M. J. Akers, *Excipient-Drug Interactions in Parenteral Formulations*, 91 J. PHARM. SCI. 2283 (2002); Paul Baldrick, *Pharmaceutical Excipient Development: The Need for Preclinical Guidance*, 32 REGULATORY TOXICOLOGY & PHARMACOLOGY 210 (2000); L. K. Golightly, et al., *Pharmaceutical Excipients: Adverse Effects Associated with Inactive Ingredients in Drug Products (Part I)*, 3(2) MED. TOXICOL. ADVERSE DRUG EXP. 128 (1988); G. Pifferi et al., *Quality and Functionality of Excipients*, 54 FARMACO 1 (1999); Y. L. Wong, *Adverse Effects of Pharmaceutical Excipients in Drug Therapy*, 22(1) ANN. ACAD. MED. SING. 99 (1993).

¹⁶⁶ See R. E. Osterberg & N. A. See, *Toxicity of Excipients—a Food and Drug Administration Perspective*, 22 INT’L J. TOXICOL. 377 (2003).

¹⁶⁷ See Mark D. Grebenau, *URGENT: Reports of Substitution of NEORAL® with Generic Equivalents of SANDIMMUNE®*, NOVARTIS-TRANSPLANT.COM, 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) (last visited Apr. 18, 2006).

¹⁶⁸ See, e.g., Trevor Cook, *Regulatory Data Collection of Medicinal Products in Europe*, BIO-SCIENCE L. REV. (Mar. 6, 2003), available at http://pharmalicensing.com/features/disp/1046957520_3e674dd06906d (stating that 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* (Mar. 2005), <http://siteresources.worldbank.org/HEALTHNUTRITIONANDPOPULATION/Resources/281627-1095698140167/HomedesGenericDrugFinal.pdf> (describing survey study discovering bioequivalence has different meanings across countries).

¹⁶⁹ See S. 334 at § 4. Note also that individual importation would also be allowed if nonbioequivalent labeling is provided. *Id.* Yet this is a highly dangerous action; if excipients make the drug 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.

From a legal perspective, the bill attempts to limit the ability of pharmaceutical companies to discriminate against entities who wish to participate in the importation program.¹⁷⁰ In effect, pharmaceutical companies would be required to sell under the same conditions to all suppliers acting as exporters and importers regardless of whether they were participating in the importation of these drugs into the US or not.¹⁷¹ Drugs must also be the same in form and packaging and not be changed to discern it from a drug for distribution in the US versus in a foreign country.¹⁷² Further, resale of a drug sold for or to a foreign entity that is then brought into the US for sale shall not be considered an act of patent infringement.¹⁷³

These provisions appear to be an effort to preclude pharmaceutical company gaming of the US intellectual property regime in an effort to stop the importation program by claiming patent infringement. Current law would allow such suits under federal precedent.¹⁷⁴ Although this might further the goal of limiting pharmaceutical company gaming, it may also have an unintended effect. Because of the difficulty with counterfeits and fakes throughout the world, it is clear that there are entities that range from the reliable to the unreliable to the downright criminal. Even if private knowledge or investigation finds that certain entities are not trustworthy, if they are registrants under the importation program, they *must* be sold to. This may place the risk of harm—pecuniary and nonpecuniary—on the patient and the pharmaceutical company if fakes are introduced through the importation program stream.

The bill attempts to circumvent potential patient harm through requiring security measures to be adopted.¹⁷⁵ Yet, harm may also occur by hasty implementation of the bill's security requirements. The bill indicates that track and trace as well as other anticounterfeiting technology are mandated to be established by regulation by the Secretary of the Department of Health and Human Services.¹⁷⁶ But the timeline for this action is, for registered importers, only 90 days from enactment of the statute.¹⁷⁷ Unfortunately, security technology is not currently available to effectively perform this function; the FDA notes that RFID and other promising technology will not be ready until at a minimum, 2007.¹⁷⁸ In fact, tests of RFID by large wholesalers have found a 27% failure rate using RFID.¹⁷⁹ With 1.39 million deliveries *a day* for one particular wholesaler,¹⁸⁰ this failure rate is entirely too high and indicates that a 90

¹⁷⁰ See *id.* at 73-74.

¹⁷¹ See *id.* at 75.

¹⁷² See *id.*

¹⁷³ See *id.* at 89.

¹⁷⁴ See generally *Jazz Photo Corp.*, 264 F.3d 1094.

¹⁷⁵ See S.334.

¹⁷⁶ See *id.* at 108-109.

¹⁷⁷ *Id.* at 110.

¹⁷⁸ Of course, this only relates to *beginning* use. FDA NEWS, *FDA Announces New Initiative to Protect the U.S. Drug Supply Through the Use of Radiofrequency Identification Technology*, Nov. 15, 2004, <http://www.fda.gov/bbs/topics/news/2004/NEW01133.html>.

¹⁷⁹ Robert P. Giacalone, *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 and distributors in the United States, found on testing that only 73% of RFID tags were readable, and that broader testing found that wholesalers had failure rates of 3.5% to 21%. It is illustrative to note that a major event in the RFID track and trace pharmaceutical effort was a pilot project announced by a single drug manufacturer, a single wholesaler (not one of the "big three"), a single technology company, for one drug. See, e.g., *SupplyScape and Unisys Pilot Pharmaceutical Industry's First Electronic Pedigree System for Commercial Drugs*, UNISYS, May 31, 2005, http://www.unisys.com/about_unisys/news_a_events/05318546.htm. It can be imagined that the costs associated with such projects will be exceedingly high, given capital costs that will be required to implement the program. Creating systems for broader industrial use will be even greater.

¹⁸⁰ See Giacalone, *supra* note 179.

day window for implementation is much too precipitous both from a government and private industry perspective.

Indeed, as Robert P. Giacalone, Vice President of Cardinal Health, registered pharmacist and lawyer, indicates, “RFID is great for tracking cardboard. But to get to actual medicine safety, much more needs to be done.”¹⁸¹ Amplifying this theme, James Christian, Vice President and Head of Global Corporate Security at Novartis International, in testimony to the House Subcommittee on Commerce, Trade, and Consumer Protection, explained that:

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

- 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.
- 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 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 then system, but later determined to be genuine, undermining any confidence in the system.¹⁸²

¹⁸¹ *Id.*

¹⁸² James Christian, Vice President and Head of Global Corporate Security, Novartis International AG, Oral Statement before the House Energy and Commerce Committee: Subcommittee on Commerce, Trade, and Consumer Protection, *Product Counterfeiting: How Fakes Are Undermining U.S. Jobs, Innovation, and Consumer Safety* (June 15, 2005) at 7-9, available at <http://energycommerce.house.gov/108/Hearings/06152005hearing1551/Christian.pdf>.

See also J. Alan Cates, *FDA’s Placebo for Counterfeit Drugs*, FRAUD PREVENTION INSTITUTE,, available at <http://www.fraudpreventioninstitute.org/FakePillsArticle.pdf>. Cates notes that “The FDA’s recent decision to use radio tags to track drug shipments from manufacturer to major wholesalers may dampen diversion of legitimate drugs. However, the real threat is not *legitimate*—but

Hence, although technological tools are being developed for security of the drug supply,¹⁸³ they are not yet ready for prime-time. This is a crucial observation that must be attended to by those who would pin their hopes for safety on the current state of technology.

Finally, the bill attempts to regulate Internet prescribing and sales. But there are significant problems with attempting to regulate the unevenness and offshore nature of Internet businesses, and there is limited power to regulate quality.¹⁸⁴ These dangers associated with Internet online pharmacies have been of concern to the federal government and members of Congress. For example, Rep. John Dingell and Rep. Bart Stupak noted that:

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.

counterfeit drugs." Note also that many in the industry still question the business case for RFID and the manufacturing benefits, and Europe lags in adoption. See Rick Lingle, *Survey: What's the Value of RFID/EPC?* PACKING WORLD MAG., Sept. 2004, http://www.packworld.com/articles/Related_Articles/18118.html (indicating that survey of manufacturing representatives indicate benefits from investment from RFID/EPC are unclear to two-thirds of survey participants); see also *Half of Manufacturing Executives Expect High Return on RFID Investment, Finds Accenture Survey*, 2004 News Releases, http://www.accenture.com/xd/xd.sp?it=enweb&xd=_dyn%5Cdynamicpressrelease_731.xml (finding only three percent of respondents are rolling out RFID implementations).

Industry specialists note other implementation challenges, such as industry agreement on a rollout timetable, technology standards, RFID tag and reader availability, and agreements on data sharing. See Kontnik, *supra* note 35, at 8. Further, countries such as Russia, with a large counterfeits problem, note that security systems will have little effect on piracy due to ability of counterfeiters to mimic security systems as well. See, e.g., translated by Dmitry Sudakov *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, available at http://english.Pravda.ru/main/18/89/357/15406_medicine.html

¹⁸³ For example, molecular tracers are progressing that provides access to flexible as well as rigid plastics. However, this still only follows packaging rather than product. See *Molecular Tracer Tags Rigid, Flexible Packaging*, IN PHARMATECHNOLOGIST, July 27, 2005, available at <http://www.in-pharmatechnologist.com/news/news-ng.asp?n=61564-molecular-tracer-tags>; and Tracey Boles, *Scanner Will Fight \$6bn Counterfeit Medicines Market*, BUS. ONLINE, Sept. 25, 2005, available at <http://www.thebusinessonline.com/Stories.aspx?StoryID=A7F19D68-049D-4EB6-894A-0E7657B18CE1&SectionID=F3B76EF0-7991-4389-B72E-D07EB5AA1CEE>.

¹⁸⁴ See 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, at 3-4, available at http://www.house.gov/commerce_democrats/Press_109/109ltr29.pdf [hereinafter Dingell].

These hearings and repeated correspondence, we have provided extensive input into how and why current policies 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. ...

[T]he 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 Sildenafil [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.¹⁸⁵

In an effort to regulate Internet pharmacies, the bill's sponsors attempt to utilize the Federation of State Medical Boards' National Clearinghouse on Internet Prescribing as the guardian of safety.¹⁸⁶ Yet the Federal of State Medical Boards had no knowledge of this role and its Clearinghouse is used to monitor unethical physician prescribing practices rather than identification of suspect Internet pharmacies.¹⁸⁷

¹⁸⁵ See *id.* at 1-2.

¹⁸⁶ The author at a Federation of State Medical Boards Patient Safety Task Force meeting notified the Federation of State Medical Boards representatives, including the President and Vice President for Legislative Affairs, about its program inclusion in S.334. They indicated that they had no knowledge of the Federation's inclusion, and that their Clearinghouse was not created for the purpose of monitoring Internet pharmacies but instead for the purpose of detecting physicians prescribing without seeing patients. Personal Communication with Jim Thompson, MD, President, and Lisa Robin, Vice President, Federation of State Medical Boards, May 12, 2005.

¹⁸⁷ *Id.*

IV. THE INTERNET, ONLINE PHARMACIES, AND THE LAW

A. INTERNET IMPORTATION

Importation of medicines is not legal at the current time.¹⁸⁸ But the counterfeit concern is, nevertheless, a growing problem in this country. This is because massive

¹⁸⁸ According to the FDA:

virtually all prescription drugs imported for personal use into the United States ... 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 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).

Letter from Randall W. Lutter, Ph.D., Assoc. Comm'r for Policy and Planning, U.S. Food and Drug Admin., to Governor Kenny Guinn, Governor of Nev. (May 20, 2005), *available at* <http://www.fda.gov/oc/opacom/hottopics/importdrugs/guinn052005.html>. FDA personnel do have some discretion regarding personal importation under certain circumstances, such as:

1. 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
2. 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

importation is occurring through Internet pharmacy purchases.¹⁸⁹ It is estimated that the US spends \$1 billion on Internet pharmacy purchases each year, and that number is increasing.¹⁹⁰

Although web sites may display Canadian or US flags, they may or may not be located in these countries, and clearly there is a question to whether drugs that are being sold are actually from these countries.¹⁹¹ For example, CanadaRx.net, a Hamilton, Ontario registered company, operates its warehouse from the Bahamas;¹⁹² Canadatrust.com was selling products that came from Mexico and were not approved by Health Canada or the FDA.¹⁹³ 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.¹⁹⁴ The remaining 795 pharmacy sites had registration information indicating a US owner (the majority) as well as those in Vietnam, the Czech Republic, and Barbados.¹⁹⁵ One international counterfeits expert has noted that:

provides evidence that the product is for the continuation of a treatment begun in a foreign country.

Office of Regulatory Affairs, U.S. Food and Drug Admin., *Subpart Coverage of Pers. Importations in Regulatory Procedures Manual*, available at http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html. However, this provision is expressly noted to not be a license for personal importation generally. *Id.*

¹⁸⁹ See Dingell, *supra* note 184, at 3. See generally Liang, *supra* note 48 (reviewing Internet vulnerabilities).

¹⁹⁰ Julie Appleby, *Canada's Cheap Drugs Not the Answer*, USA TODAY, Aug. 28, 2003, available at http://www.usatoday.com/tech/news/2003-08-27-canadadrugs_x.htm. This use of Internet pharmacies is a tremendous safety issue because, amongst other things, children are using these sites to obtain drugs for abuse. See, e.g., *Crack Down on Online Pharmacies that are Selling Drugs to Kids*, DEMOCRAT & CHRON., Aug. 5, 2005, available at <http://www.democratandchronicle.com/apps/pbcs.dll/article?AID=/20050805/OPINION04/508050365/1041/OPINION> (describing National Center on Addiction and Substance Abuse study reporting abuse by children of oxycontin and Ritalin obtained through online pharmacies).

¹⁹¹ Pfizer and Microsoft have joined forces to prosecute international spam syndicates that attempt to sell counterfeit Viagra. CanadianPharmacy is one entity targeted by Pfizer and Microsoft. The identities of the individuals controlling these sites are unknown, while the drugs and purchasing supply chain "spans the globe", including India, which is notorious for its fake drug supply. See, e.g., John Leyden, *Pfizer and MS Sue Viagra Span Gangs*, REGISTER (UK), Feb. 10, 2005, available at http://www.theregister.co.uk/2005/02/10/spam_lawsuit. The difficulty in finding counterfeiters is tremendous, particularly on the Internet. A web address may be licensed in Russia; the server in China; the company payee for the credit card charge in the UK; the processing of payment in Australia; and the product mailed from Chicago, using a return address of a unwitting customer of the website. See Christopher Rowland, *Drug Makers Press Fight vs. Counterfeiters*, BOSTON GLOBE, Feb. 14, 2005, available at http://www.boston.com/news/globe/health_science/articles/2005/02/14/drug_makers_press_fight_vs_counterfeiters/.

¹⁹² See Christopher Rowland, *Drugs From Anywhere: As Importation Networks Spread, Concerns for Consumer Safety Grow*, BOSTON GLOBE, Dec. 16, 2004, available at http://www.boston.com/news/world/articles/2004/12/16/drugs_from_anywhere?pg=full.

¹⁹³ See SHEPHERD, *supra* note 29, at 10.

¹⁹⁴ See Ricardo Alonso-Zaldivar, *FDA Casts Suspicion on Online Pharmacies*, SEATTLE TIMES, June 15, 2005, available at http://seattletimes.nwsource.com/html/nationworld/2002336462_fda15.html. See Jeff Clabaugh, *Survey Finds Few Online Pharmacies Sell Drugs*, WASH. BUS. J., June 13, 2005, available at <http://www.bizjournals.com/washington/stories/2005/06/13/daily3.html>. Cyveillance notes that online brand abuses seen "a lot" are in the pharmaceutical industry. See Donna Howell, *Cyber Sleuths Monitor Internet's Action On Lookout For Crooks Cyveillance Seeks Fraud Schemes, Illegal Uses of Clients' Brands, Products*, INVESTOR'S BUS. DAILY, Aug. 4, 2005.

¹⁹⁵ See Alonso-Zaldivar, *supra* note 194.

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 likelihood of drugs being time-expired or incorrectly stored are extremely high.¹⁹⁶

It bears emphasizing once again that drugs shipped through countries like Canada and Western Europe are not subject to those countries' health safety laws if the products are not earmarked for domestic consumption.¹⁹⁷ This legal reality puts in stark relief how international counterfeit market implications can arrive in our very own mailboxes and homes. It also indicates the vulnerability of the drug supply to inadequate conditions, storage, and other factors that could affect the efficacy of the drugs—and their effects, if taken, can be life-threatening.¹⁹⁸

In addition, the law has had tremendous difficulties in protecting consumers from counterfeits by failing to hold Internet portals of purchase accountable for their sales.¹⁹⁹ Consumers both here and around the world, including Europe,²⁰⁰ cheated and harmed by rogue Internet pharmacies selling tainted and fake drugs, have little recourse against these offshore facilities, which may simply sprout up again in another form, even assuming the site has closed.²⁰¹ According to William Hubbard, Associate Commissioner for Policy and Planning at the FDA, the "FDA has no ability to take effective action against these foreign operators on behalf of US citizens."²⁰²

Rogue Internet and mail order pharmacies are seen to be the primary source of counterfeit drugs within the next five years.²⁰³ Documented examples of rogue Internet pharmacy counterfeit sales in the US include:

¹⁹⁶ See *Top European Security Expert Warns Senate Panel on Risk of Drug Importation; Urges Congress to Learn from Problems Faced by European Union*, PHARMALIVE, Apr. 19, 2005.

¹⁹⁷ See *supra* notes 117-119 and accompanying text.

¹⁹⁸ See, e.g., Deanna Lites, *Medication Meltdown*, WHDH-TV, Aug. 23, 2005, available at <http://www1.whdh.com/features/articles/healthcast/BOS4011> (describing effects of poor conditions for transport and storage of medications that can result in therapeutic failure and side effects).

¹⁹⁹ "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 in enforcing the law against foreign sellers, when they are hard to reach and outside our borders." Statement of William K. Hubbard, Assoc. Comm'r for Policy and Planning, Committee on Gov't Reform, U.S. House of Representatives, Hearing on Internet Drug Sales, Mar. 18, 2004, available at <http://www.fda.gov/ola/2004/Internetdrugs0318.html>.

²⁰⁰ "Potent 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://www.emediawire.com/releases/2005/3/emw219649.htm> [hereinafter *Global Forum*].

²⁰¹ Statement of William K. Hubbard, Ass. Comm'r for Policy and Planning, Before the Comm. on Government Reform, U.S. House of Representatives, Hearing on Internet Drug Sales, Mar. 18, 2004, available at <http://www.fda.gov/ola/2004/Internetdrugs0318.html>.

²⁰² Charles W. Schmidt, *Phony Pharm*, MOD. DRUG DISCOVERY, Nov. 2002, at 27, 28 (quoting William K. Hubbard, during a Senate committee hearing, July 9, 2002), available at <http://pubs.acs.org/subscribe/journals/mdd/v05/i11/pdf/1102rules.pdf?sessid=600613>.

²⁰³ *Online, Mail-Order Firms Fastest Growing Sources of Counterfeit Drugs*, IHEALTHBEAT, Apr. 28, 2005, <http://www.ihealthbeat.org/index.cfm?Action=dspItem&itemID=110666>. See, e.g., Suzanne Gamboa, *DEA Cracks Down on Illegal Rx Web Site*, BIZ REPORT, Sept. 21, 2005, <http://www.bizreport.com/print/9312/> (discussing DEA arrest of at least 18 persons, registrations

- counterfeit contraceptive patches from India using web site names such as www.usarstore.com, www.europeanrxpharmacy.com, and www.generic.com; and
- counterfeit 1,4 butanediol (a precursor of gammahydroxybutyric acid, which is a schedule I drug), growth hormone, 4 bromo-2,5 dimethoxyphenethylamine (a schedule I drug), tiratricol (a thyroid hormone), using the web site name genapharm.com.²⁰⁴

Government drug importation web sites also disclaim liability for medicines purchased therefrom. For example, the State of Washington's Canadian drug purchasing website indicates that:

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.²⁰⁵

Other states such as Minnesota and Illinois have similar provisions.²⁰⁶

As Secretary of the Department of Health and Human Services Michael O. Leavitt has explained:

suspensions of 20 physicians and 22 Internet pharmacies, shutdown of 4,600 web sites, seizure of 2,400 checks and money orders, and legal proceedings to seize several homes worth \$7.85 million in sting on illegal Internet pharmacy business).

²⁰⁴ Statement of William K. Hubbard, *supra* note 202. See also Audra Ang, *Twelve Arrested in International Drug Scheme*, BOSTON GLOBE, Sept. 8, 2005, available at http://www.boston.com/news/world/asia/articles/2005/09/08/12_arrested_in_international_drug_scheme (describing a \$4.3 million counterfeit drug operation that sold drugs to patients in Britain, Israel, Switzerland, and the U.S. through the Internet).

²⁰⁵ Prescription Drug Program, Washington State Health Care Authority, Accessing Canadian Pharmacies, <http://www.rx.wa.gov/prescriptionhelp/canada.shtml> (last visited Apr. 18, 2006).

²⁰⁶ "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." See Minnesota RxConnect Online, Legal Information, <http://www.state.mn.us/cgi-bin/portal/mn/jsp/content.do?programid=536902438&agency=Rx> (last visited Apr. 18, 2006). "[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." See I-SaveRx, Order Form, http://www.i-saverx.net/assetsrx/il_enrollment.pdf (last visited Apr. 18, 2006).

You could go onto our [I]nternet 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. 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.²⁰⁷

Hence, the problem of fraudulent Internet pharmacy sales is increasing.²⁰⁸ Personal importation through the Internet has created a system where accountability is absent, and patients—even under the auspice of a state purchasing program—take their own risks and shoulder the burden of counterfeit and tainted drugs.

V. REFORM

A. COOPERATION AND EMPOWERMENT

Drugs must be authentic and safe to provide the benefit of improved life. Counterfeits are not only cheating patients of that benefit, they are also often exposing them to harmful agents. Weaknesses of the drug distribution and legal systems should be addressed to protect patients from harm. Internet pharmacies and importation efforts should be closely scrutinized to ensure we err on the side of safety to limit the international gray and black markets and unscrupulous individuals preying on the ill.

It bears emphasizing that we need safe, affordable drugs. Affordability is important, but safety must come first. International cooperative efforts, technology, and patient empowerment must be coordinated to erect barriers to harm from counterfeit drugs.

As a first step, law enforcement, health care providers, and public health and safety agencies internationally should cooperate and establish standardized regulations, operations, and reporting infrastructures supported by heavy criminal penalties, in order to effectively deal with importation and its relation to counterfeit

²⁰⁷ See Dingell, *supra* note 184.

²⁰⁸ “There are tens of thousands of Web sites that sell prescription drugs of unknown origin to Americans illegally. . . . A Web site based in Canada may get its products from India or China, or may traffic in counterfeits.” Matthew Herper, *Bad Medicine*, FORBES, May 23, 2005, available at http://www.forbes.com/home_europe/free_forbes/2005/0523/202.html. Further, “Argentinean export records seem to show tens of thousands of doses of drugs, including knockoffs of erythropoietin and the cancer drugs Eloxatin and methotrexate, making their way from Argentina into Canada.” *Id.*

drugs.²⁰⁹ This is one area where policymakers, industry, and investigators apparently agree. Dr. Lembit Rāgo of the WHO has stated that “Such a framework would enable regulation, demonstrate political commitment and will to establish policy and regulation to address the problem, put into place criminal law and sanctions and facilitate cooperation between different law enforcement agencies.”²¹⁰

Julian Mount, Senior Director of European Trade at Pfizer, Inc., also calls for such action: “[T]here is a need for stakeholder accountability, uniform systems and regulation leading to accountable supply chain management by all players delivering medicines to patients in Europe. This means pan-European legislation, regulatory coordination, appropriate technologies, and the need to better enforce the repackaging of medicines to ensure patient safety and medicine integrity.”²¹¹ Counterfeiting investigators echo this response, saying “As long as the fight against counterfeits is not a concerted effort, criminals will be able to exploit the loopholes in the system. The fight includes prevention measures by manufacturers, communication and effective education of professionals and patients, and ensuring that punishments are appropriate to this deadly crime.”²¹² Hence, communication and harmonization of efforts are vital to counter the sale and harm from counterfeit medications around the world.²¹³

Communication should include a joint enterprise of stakeholders via a robust and simple reporting system. In concert with public health campaigns and provider education to raise awareness of the potential presence of counterfeit drugs, creating an international reporting system involving patients, providers, law enforcement and investigation personnel, public health officials, and others would provide extremely valuable information on the epidemiology of fake and counterfeit drugs.²¹⁴ This in turn would provide public officials with critical data to disseminate for citizen protection, provider awareness, as well as early potential detection for law enforcement investigation.

It should be strongly emphasized that criminal investigation activities are an essential element for information sharing across borders in order to ferret out and punish those persons trading in the counterfeit medicine arena.²¹⁵ This market clearly

²⁰⁹ See *Global Forum*, *supra* note 200. For a more detailed interdisciplinary strategy, see generally Liang, *supra* note 48. For an assessment of the limits of technology, see Bryan A. Liang, *Structurally Sophisticated or Lamentably Limited? Mechanisms to Ensure Safety of the Medicine Supply*, ALB. L. J. SCI. & TECH. (2006), forthcoming.

²¹⁰ *Id.*

²¹¹ *Id.*

²¹² *Id.* (quoting Ian Lancaster, Director, Reconnaissance International, specialists in anticounterfeiting strategies).

²¹³ Reporting systems in the U.S., such as MedWatch, should be coordinated with other international sites. The International Pharmaceutical Federation announced that it will create a website to target counterfeit medicine, and includes a means for counterfeit reporting. *FIP Website Tackles Fake Drug Peddlers*, IN-PHARMA TECHNOLOGIST, Mar. 12, 2005, <http://www.in-pharmatechnologist.com/news/news-ng.asp?n=58730-fip-website-tackles>. This site was spurred by the expanding reach of counterfeits in developing countries, including antibiotics, painkillers, and even multivitamins. See *Fake Drugs Spreading Rapidly, Warns WHO*, MSNBC, May 6, 2005, <http://msnbc.msn.com/id/7761725>.

²¹⁴ Reporting systems for patient safety and aviation safety have been created that have garnered thousands of reports each year. See Bryan A. Liang, *Risks of Reporting Sentinel Events*, 19(5) HEALTH AFF. 112-120 (2000) (describing reports from the Aviation Safety Reporting System); see Pennsylvania Patient Safety Authority, Annual Report for 2004, available at <http://www.psa.state.pa.us/psa/cwp/view.asp?a=1275&q=445714> (last visited Apr. 18, 2006).

²¹⁵ A preventive strategy, such as limiting online pharmaceutical sales to online pharmacies that have established their compliance with national safety standards, could assist greatly. A bill to create such a requirement has been introduced in Congress. *Walden, Davis Re-Introduce Rx Safety*

does not respect international lines and hence, neither can efforts to eliminate it. In concert with sentiments noted above, criminal penalties for manufacture, sale, and distribution of counterfeit drugs must at least be akin to similar activities involving illicit drugs such as heroin and cocaine. Greater penalties would be preferable, and indeed, consideration of life imprisonment for perpetrators,²¹⁶ as well as forfeiture of all assets and treble damage assessments. Penalties must be as severe as the potential harm that results.

Supporting cooperative efforts, technological standardization and implementation of methods such as radio frequency ID tags, holograms, and other methods to ensure appropriate pedigree and identification of valid drugs, should be supported so that scrupulous suppliers can stay ahead of counterfeiters. Research and development for these methods should have significant public and private investment, and should be coupled with international efforts and standards to harmonize their applicability. However, it should be emphasized that although there is promise in technology, currently technology is not a panacea to address the problem of counterfeit drugs.²¹⁷ The weaknesses in the state of the art in this area highlights the need for immediate attention to this issue.

Patients should also realize that they are the last barrier to harm from these counterfeits.²¹⁸ For example, consistently using a safety checklist like SAFE DRUG,²¹⁹ available at the Partnership for Safe Medicines website, can reduce the chances of harm from counterfeit medications. It focuses upon using Samples to determine baseline responses and information about drugs, checking Appearance of the drug each time it is taken, noting the Feel and taste of the drug at each administration while recording it down in a medication diary, and Evaluating the drug with respect to feel, taste, and medium term response.²²⁰ If a problem is suspected, patients should call their Doctor—and have a low threshold for suspicion.²²¹ Patients should Report the drug to the relevant authorities (e.g., FDA, law enforcement, manufacturer, local pharmacy where purchased).²²² Make the drug

Bill: Legislation Would Protect Americans by Establishing Safety Standards for Web-Based Pharmacies, BEND, Apr. 23, 2005, http://bend.com/news/ar_view.php?ar_id=22371 (describing H.R. 1808, the Safe Online Drug Act of 2005).

²¹⁶ One state is considering such a bill. See David Pitt, *Iowa House Passes Law Against Making Counterfeit Drugs*, WATERLOO CEDAR FALLS COURIER, Apr. 22, 2005, available at http://www.wfcourier.com/articles/2005/04/22/news/breaking_news/doc4268d24b27870940659285.txt (discussing possible life sentence in prison for involvement in sale of counterfeit drugs resulting in death). See also *Counterfeit Drug Prevention Act of 2006*, H.R. 5156, 109th Cong., 2nd Sess. (2006) (increasing counterfeiting penalties to 20 years imprisonment, and up to life imprisonment if a counterfeit drug is the proximate cause of consumer death).

²¹⁷ See *supra* notes 178-182 and accompanying text (reviewing limitations of security technology).

²¹⁸ Note also that patients are the last barrier to harm from medication errors in dispensing, and all medication dispensing is subject to human error. See, e.g., Amelia Graham, *6 News Discovers More Trouble with Prescriptions from Local Pharmacy*, WATE-TV (TN), July 14, 2005, available at <http://www.wate.com/Global/story.asp?S=3595262> (describing medication error by CVS pharmacy). Detection and safety require redundancy of human processes that accept that error will occur and implement a system that can block that error from resulting in harm. See Bryan A. Liang, *Special Report: Medical Errors Part I—Reporting the Wrench*, S. CAL. PHYSICIAN 19, 20-1 (Apr. 2005), available at <http://socalphys.com/site/apr05/feature2.pdf> (describing systems processes).

²¹⁹ Partnership for Safe Medicines, <http://www.safemedicines.org> (last visited Apr. 18, 2006). See, e.g., Don Oldenberg, *Raising the Alarm on Rise in Counterfeit Drugs*, WASH. POST, Apr. 5, 2005, at C9 (discussing the SAFE DRUG checklist of safety tips).

²²⁰ *Id.*

²²¹ *Id.*

²²² *Id.*

Unavailable by taking it out of the medicine cabinet, taping the top shut, and marking it with an X in red so it will not be confused with legitimate drugs.²²³ Finally, patients should give details of their experience by collecting all the materials (e.g., packaging, package insert, remaining pills) and provide information to law enforcement, the FDA through the MEDWATCH web site, and others to allow thorough investigations to occur so that others will be protected by it.²²⁴ Indeed, consumers are a critical part of the counterfeit detection team; it was consumers who first alerted authorities to counterfeit Lipitor in the US.²²⁵

Further, beyond self-detection and protection, being empowered through information about potential fake or counterfeit medications may also provide an early warning for consumers to be alert for drugs that may affect them. The Food and Drug Administration does publish counterfeit alerts.²²⁶ However, patient access requires constant checking of the FDA website. Other services such as the SafeMeds Alert System, which is an email notification system for detected fake drugs sent to individuals who sign up, may be another, more effective tool to allow consumers to be actively informed and give them information to protect themselves and their families.²²⁷

²²³ *Id.*

²²⁴ *Id.*

²²⁵ See Theriault, *supra* note 115.

²²⁶ See, e.g., Food and Drug Administration, Recalls, Market Withdrawals and Safety Alerts Archive, <http://www.fda.gov/opacom/7alerts.html> (last visited Apr. 18, 2006). Note that these alerts cover all aspects of FDA activities, such notifications on food safety. Hence, pharmaceutical safety is only a subset of information disseminated. The FDA has also announced the formation of a Counterfeit Alert Network, which will provide information to co-sponsor organizations and their members, including consumer groups. Currently the system is limited to entities; individuals cannot sign up to be part of the notification system. See Food and Drug Administration, *Combating Counterfeit Drugs: A Report of the Food and Drug Administration Annual Update*, May 18, 2005, available at <http://www.fda.gov/oc/initiatives/counterfeit/update2005.html>.

A promising approach for areas with limited personal Internet access was announced by the World Health Organization, which will create a web-based system to track fake drugs and disseminate information to national authorities for action. *WHO Launches Web-Based System to Track Fake Drugs*, CTV (Canada), May 3, 2005, http://www.ctv.ca/servlet/ArticleNews/story/CTVNews/1115117564266_14/?hub=Health. It is essentially a clearinghouse of information; reports sent/emailed/faxed and communicated to it are then disseminated to national authorities. However, the system does not reach individual consumers, primarily because the region to be served, Southeast Asia, has a technology deficit. Burma has only 0.5 Internet users per 1,000, Cambodia has 2.2 per 1,000, and Laos has 2.7 per 1,000, compared to technologically savvy countries, like Singapore which has 504 Internet users per 1,000 and Malaysia with 320 per 1,000. Marwaan Macan-Markar, *Fake Drugs in Poor Nations Worry Health Experts*, CYBER DYARYO, May 16, 2005, http://www.cyberdyaryo.com/features/f2005_0516_03.htm.

²²⁷ *Partnership for Safe Medicines Introduces First Consumer Counterfeit Drug Alert System*, PRNEWswire, June 13, 2005, <http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=109&STORY=/www/story/06-13-2005/0003868132&EDATE=> .

Price must also be addressed in the context of safety.²²⁸ First, the Medicare Modernization Act's provisions may be of great assistance to seniors who, as the greatest users of medicines, face the challenge of paying for pharmaceutical treatments.²²⁹ However, because of the "doughnut" hole in Medicare drug coverage (where annual costs between \$2,250 and \$5,100 will not be reimbursed)²³⁰ and for all others who face the expense of pharmaceutical costs, other means to reduce costs safely, using the domestically traced supply, should be created and disseminated. This consideration is amplified for seniors because foreign-bought drug costs will not be covered by the Medicare drug program.²³¹

There are a variety of state hybrid efforts that utilize the domestically regulated drug supply to provide significantly discounted medicines. For example, programs such as the Illinois Pharmacists Association Rx-for-Illinois²³² and state-nonprofit-private Rx-for-Indiana²³³ program serve as sources for their citizens to obtain affordable medicines. Other state programs provide discounts and, importantly, also allow for screening of potential drug-drug interactions when each prescription is filled.²³⁴ As well, each pharmaceutical company itself offers programs—perhaps not well publicized due to loss of revenues—that also provide cheaper medicine access.²³⁵ These latter programs are now becoming more publicized, some speculate due to the potential of drug price controls.²³⁶

²²⁸ It is interesting to note that Canadian analysis indicates that lower prices in Canada may not be from price controls, but in fact due to the lower standard of living in Canada in comparison to the United States and other industrialized countries, including France, Switzerland, the United Kingdom, Sweden, and Italy. Also, Canadians face higher generics prices than U.S. citizens. See JOHN R. GRAHAM & BEVERLY A. ROBSON, PRESCRIPTION DRUG PRICES IN CANADA AND THE UNITED STATES—PART 1: A COMPARATIVE SURVEY, 42 PUB. POL'Y SOURCES, Sept. 25, 2000, [http://www.fraserinstitute.ca/admin/books/files/PrDrgPr1\(42\).pdf](http://www.fraserinstitute.ca/admin/books/files/PrDrgPr1(42).pdf); JOHN R. GRAHAM, PRESCRIPTION DRUG PRICES IN CANADA AND THE UNITED STATES—PART 2: WHY THE DIFFERENCE?, 43 PUBLIC POL'Y SOURCES, Sept. 25, 2000, [http://www.fraserinstitute.ca/admin/books/files/PrDrgPr2\(43\).pdf](http://www.fraserinstitute.ca/admin/books/files/PrDrgPr2(43).pdf). See also Ricardo Alonso-Zaldivar, *For Generic Drugs, the Price Is Right in US*, L.A. TIMES, Aug. 9, 2005, available at <http://www.americaputmeoutofbusiness.com/news-aug-09-05-003.php> (reporting that generics up to 78% more expensive in Canada).

²²⁹ See, e.g., Erin Julius, *Help for Prescriptions is on the Way: Medicare to Offer Insurance Coverage for Medication*, NEWS LEADER, July 13, 2005, available at <http://www.newsleader.com/apps/pbcs.dll/article?AID=/20050713/NEWS01/507130321/1002> (describing Medicare Modernization drug coverage as well as additional financial coverage for eligible Medicare beneficiaries).

²³⁰ In the Medicare drug program, after paying a monthly premium of roughly \$37/month and a \$250 deductible, Medicare beneficiaries will have 75% of drug costs for the next \$2,000 covered under the plan. From that \$2,000 level up to \$5,100 in drug costs, the program will cover nothing. Finally, above the \$5,100 level of drug costs, the program will cover 95% of prescription drug costs. See Centers for Medicare & Medicaid Serv., Drug Coverage, <http://www.cms.hhs.gov/medlearn/drugcoverage.asp> (last visited Apr. 18, 2006).

²³¹ See Mary Massingale, *Medicare may cut appeal of I-SaveRX: New Drug Plan Won't Count Meds Purchased Abroad*, STATE-JOURNAL REGISTER, July 5, 2005. Note also that credit card purchases for Canadian drugs may subject the US consumer to transaction fees. See *Senior Charged Fee to Buy Canadian Prescriptions*, NBC 10 (Penn.), Aug. 18, 2005, <http://www.nbc10.com/consumeralert/4869614/detail.html> (last visited Apr. 18, 2006).

²³² See RxForIllinois, <http://www.rxforillinois.org> (last visited Apr. 18, 2006).

²³³ See RxForIndiana, <http://www.rxforindiana.org> (last visited Apr. 18, 2006).

²³⁴ See Stacy Forster, *Program Saving Money on Drugs; But Badger Rx Gold Isn't Cheaper for Everyone*, MILWAUKEE J. SENTINEL, Aug. 6, 2005, <http://www.jsonline.com/news/state/aug05/346695.asp> (describing Wisconsin state program Badger Rx which provides access to discounted drugs and monitors patient prescription for potential drug-drug adverse interactions) (last visited Apr. 18, 2006).

²³⁵ See *supra* notes 203-210 and accompanying text (discussing domestic alternatives for affordable medicines).

²³⁶ *Id.*

These discount programs utilizing domestic supplies introduced by states and nonprofit entities such as pharmacist associations, and some in cooperation with pharmaceutical companies, are an excellent start.²³⁷ Such programs, which often target the uninsured and the state's low income citizens, are usually based on a clearinghouse model. Programs are accessible through a toll-free phone number or web page and have no enrollment costs.²³⁸ They obtain demographic information and then assist in matching patients with eligible discount plans as well as filling out enrollment forms.²³⁹ Other models formed by a consortium of public and private provider, charitable, and corporate groups, including pharmaceutical companies, also expand services beyond discount drug programs to foreign language access and provision of information on Medicaid program enrollment, and state and federal low cost health insurance programs.²⁴⁰ In addition to state programs, the pharmaceutical industry itself has launched a national independent clearinghouse program in conjunction with community and provider partners, called the Partnership for Prescription Assistance, to assist in providing access to affordable medicines.²⁴¹ Other independent clearinghouse programs are also becoming available.²⁴² It is

²³⁷ Particularly in the context that widespread, legalized importation may not be the price-reducing panacea for US consumers. *See, e.g.*, TASK FORCE, *supra* note 10, at 37-38; *see also* CONGRESSIONAL BUDGET OFFICE COST ESTIMATE: H.R. 2427 THE PHARMACEUTICAL MARKET ACCESS ACT OF 2003 (Nov. 19, 2003), <http://www.cbo.gov/graphics/pdf-off.gif> (estimating saving from prescription drug importation at less than 10% of claimed estimates under Pharmaceutical Market Access Act of 2003, an earlier importation bill) (last visited Dec. 5, 2004).

²³⁸ *See, e.g.*, Deanna Wren, *33,000 Quality for Drug Aid in Initial Week of Web Site*, FT. WAYNE J. GAZETTE, Mar. 19, 2005, available at 2005 WLNR 4390951. Note that the Department of Health and Human Services Office of Inspector General has indicated that prescription assistance programs for needy Medicare Part D beneficiaries are permissible without running afoul of fraud and abuse laws. *See* U.S. Dept. of Health and Human Services, *HHS Applauds Pharmaceutical Patient Assistance Programs*, April 18, 2006, available at: <http://www.hhs.gov/news/press/2006pres/20060418a.html>.

²³⁹ *See, e.g.*, *supra* notes 235 & 236 and accompanying text.

²⁴⁰ *See, e.g.*, *Millions Access Free or Deeply Discounted Prescription Medications Through RX HELP for CALIFORNIANS*, PHARMALIVE, Mar. 16, 2005, available at <http://www.forrelease.com/D20050316/sfw073.P2.03162005130634.03156.html> (describing the rxhelpforca.org site, providing translation for 15 languages and assistance in enrollment in the state Medicaid program). Similar clearinghouse programs also exist in Ohio, Rhode Island, Washington, West Virginia, and Washington, DC. *Id.* *See also* Jennifer Maloney, *Drug Card Gives \$3M Dose of Savings*, NEWSDAY, Aug. 24, 2005, at A26, available at 2005 WLNR 13314284 (describing Nassau County discount card NassauRx program).

²⁴¹ Partnership for Prescription Assistance, <http://www.pparx.org>. Pharmaceutical companies have also created an independent program known as Together Rx, www.togetherrxaccess.com, which also provides discounted pharmaceuticals to patients using a discount card. *See, e.g.*, Together Rx Access Launches Ads to Encourage Americans with No Prescription Drug Coverage to Enroll in Savings Program, http://togetherrxaccess.com/en/pressroom/TRx_Access_PR_25Apr05.pdf. The Partnership for Prescription Assistance has been reported to have aided more than 600,000 people over three months; the state of New Jersey, which is a state chapter of the Partnership for Prescription Assistance, has provided assistance for greater than 80,000 as of July 2005. *See* Jeff May, Ed Silverman & George E. Jordan, *Needy Get a Short in the Arm on Rx Aid*, STAR-LEDGER, July 28, 2005, available at 2005 WLNR 11854353.

²⁴² *See, e.g.*, Partnership for Safe Medicines, <http://www.safemedicines.org>, a site that describes programs such as HelpingPatients.org, RxOutreach.com, and TogetherRx.com in its Safe Savings Brochure. Although clearinghouse programs would appear to be the most effective in creating affordable prices for medicines using domestic supplies, other methods may also be effective in reducing the financial burden of pharmaceutical treatments. In conjunction with comparison shopping through web sites such as PillBot.com and DestinationRx.com, as well as focus on the use of generics, samples, and other options can reduce medication costs. *See id.* State creation and support of comparison shopping sites could also provide incentives for lower prices while utilizing the domestic supply. *See, e.g.*, *Attorney General Unveils Drug Site*, CINCINNATI BUS. COURIER, Apr. 5, 2005,

interesting to note that state-funded and supported Canadian purchase programs have not garnered significant demand, whereas these clearinghouse programs using domestic supplies have been quite popular.²⁴³ These latter plans, in combination with other efforts,²⁴⁴ represent a foundation and should be consolidated and/or expanded to provide meaningful access to safe, affordable medicines for all those who need them.

B. DEEPER ISSUES

Deeper issues surround the debate around importation. First, the high prices for pharmaceuticals in the United States, as well as other countries,²⁴⁵ create access problems. Of course, it is clear that it is exceedingly expensive to bring a molecule from the laboratory bench to the market; estimates place the costs at \$800-900 million.²⁴⁶ This cost should be considered in the context that, according to aggregate industry statistics, only 1 out of roughly 5,000 molecules tested ever reaches the level of patient use and takes an estimated 12 to 15 years to bring to market.²⁴⁷ Only roughly 30% of drugs actually approved for patient use result in revenues adequate to cover the costs of their development.²⁴⁸ Due to the high financial stakes, brand name pharmaceutical companies lobby and advertise heavily to ensure prices may be

available at <http://cincinnati.bizjournals.com/cincinnati/stories/2005/04/04/daily18.html> (describing Ohio Attorney General Jim Petro's consumer site, <http://www.ag.state.oh.us>, that allows comparison shopping for 25 common prescription drugs that has attracted greater than 200 competing pharmacies); *New York Rx Price Posting Law is Most Comprehensive in Nation*, ARRIVENET, Aug. 1, 2005, <http://press.arrivenet.com/pol/article.php/676855.html> (describing New York State program that provides comprehensive listing of retail prescription drug prices of 150 most prescribed drug from every pharmacy in the state, updated weekly). The Centers for Medicare and Medicaid Services will also create a prescription drug price comparison site when it rolls out Medicare Part D. See *CMS Previews Online Tool to Compare Drug Costs*, IHEALTHBEAT.ORG, Aug. 2, 2005, <http://www.ihealthbeat.org/index.cfm?Action=dspItem&itemID=113132>.

²⁴³ See Christopher Conkey, *States' Bid for Cheaper Medicine Sputters*, WALL ST. J., Feb. 14, 2005, available at <http://online.wsj.com/article/0..SB110835072729353797.00.html?mod=health%5Fhome%5Fstories> (describing limited foreign drug purchasing from state web sites due to concerns about drug safety, a weaker dollar, and consumer confusion); Jim Ritter, *Gov Gives Drug Plan a Shot in the Arm*, CHI. SUN-TIMES, Mar. 14, 2005, available at 2005 WLNR 4837745 (describing state I-Save-RX plan which has signed up only 3,000 persons, compared with competing Illinois Pharmacists Association clearinghouse program Rx-for-Illinois, which "has helped more than 180,000 residents.").

²⁴⁴ Such as generic purchases, comparison shopping using price tools available on the Internet, and other strategies. See *Safe Savings Brochure*, <http://www.safemedicines.org>; see also Maria M. Perontin, *Patient Cut Drug Costs in Half*, BRADENTON HERALD, July 25, 2005, available at <http://www.bradenton.com/mld/bradenton/news/local/12215970.htm> (describing pill splitting programs to reduce medication costs); *Prescription Drug Savings Available Through AAA*, July 27, 2005, <http://www.aaanewsroom.net/Main/Default.asp?PageSearchEnginePageSize=&LoosenSearch=&FileSearchEnginePageSize=&ArticleSearchEnginePageSize=&CategoryID=8&ArticleID=388> (describing AAA discount drug program available to any person or family).

²⁴⁵ See Nunez-Diaz, *supra* note 42 (noting that only 30% of Peruvians have access the drugs due to high costs, thus fueling counterfeit production and sales).

²⁴⁶ U.S. Food and Drug Administration, *FY 2003 Performance Report to the President and the Congress*, <http://www.fda.gov/oc/pdufa/report2003/default.htm> (\$800 million) (last visited Apr. 18, 2006) [hereinafter FY 2003]; Tufts Center for the Study of Drug Development, *Total Costs to Develop a New Prescription Drug, Including Cost of Post-Approval Research, is \$897 Million*, May 13, 2003, <http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=29>.

²⁴⁷ Pharmaceutical Research and Manufacturers of America, *Why Do Medicines Cost So Much?*, http://lobby.la.psu.edu/002_Patent_Extension/Organizational_Statements/PhRMA/Why.htm (last visited Apr. 18, 2006).

²⁴⁸ See FY 2003, *supra* note 246.

set independently and that consumers consider their particular drugs for use.²⁴⁹ Hence, research and development, lobbying, and advertisement create almost unfathomable costs that must be recouped through drug sales.

Of course, the time limit for this recoupment is limited. In general, brand name pharmaceutical companies must develop profits during the period under which these innovative drugs are protected from competition by patent protection.²⁵⁰ Hence, prices must be calculated to cover the costs indicated above, as well as additional promising molecule development, all compressed into the period during which the brand name firm has exclusivity in sales.²⁵¹ Since generic forms of the brand name drug introduced after patent expiry are much cheaper and result in almost complete substitution away from the brand name drug,²⁵² brand name companies must get while the getting is good—during the patent protection period.²⁵³

Other countries of the world, or more accurately, their citizens, do not face the same pricing dynamic as that of the US. Virtually every other country in the world has some form of price control policy for pharmaceuticals.²⁵⁴ Hence, pharmaceutical companies do not have the power—regardless of their ability to exclude during their

²⁴⁹ Michele L. Creech, *Comment: Make a Run for the Border: Why the United States Government is Looking to the International Market for Affordable Prescription Drugs*, 15 EMORY INT'L L. REV. 593, 608 (2001).

²⁵⁰ See, e.g., Richard G. Frank & David S. Salkever, *Generic Entry and the Price of Pharmaceuticals*, 6 J. ECON. & MGMT. STRATEGY 75 (1997).

²⁵¹ In the U.S., the patent period for pharmaceuticals is generally 20 years from patent filing, 35 U.S.C. §154 (2005). However, the period in practical terms is often much less due to the period required to obtain FDA approval.

²⁵² See *id.* See also Richard E. Caves, et al., *Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry*, in BROOKINGS PAPERS ON ECONOMIC ACTIVITY, MICROECONOMICS, (Martin Neil Baily & Clifford Winston eds., 1991), available at <http://www.jstor.org/cgi-bin/jstor/printpage/10578641/di009484/00p00183/0-150.pdf?backcontext=page&dowhat=Acrobat&config=jstor&userID=a87a5060@bu.edu/01cc99333c1b94f108f2f31056&0-150.pdf> (generic drug entry results in substitution and increasing drug price reductions as additional generic forms enter).

²⁵³ Note that brand name companies are also attempting to extend their hold on markets they obtained through introduction of their new drugs past patent expiration. This process, through issuing—or threatening to issue—their own generic form of the drug, sometimes known as “pseudogenerics”, “authorized generics”, or “branded generics”, has become a hotly contentious issue regarding the pro- or anti-competitive effects of this practice. The Federal Trade Commission has come down on both sides of this issue, depending on the facts of the particular case. See, e.g., FEDERAL TRADE COMMISSION, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY* (July 2002), <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>. Other commentators have been firmly against the practice; see, e.g., Bryan A. Liang, *The Anticompetitive Nature of Brand-Name Firm Introduction of Generics Before Patent Expiration*, THE ANTITRUST BULLETIN: THE JOURNAL OF AMERICAN AND FOREIGN ANTITRUST AND TRADE REGULATION 599 (Fall 1996) (illustrating the U.S. markets' perspective); Aiden Hollis, *The Anti-Competitive Effects of Brand-Controlled 'Pseudo-Generics' in the Canadian Pharmaceutical Market*, 29(1) CANADIAN PUBLIC POL'Y 21 (2003), available at <http://economics.ca/cgi/jab?journal=cpp&view=v29n1/CPV29n1p021.pdf> (illustrating the Canadian markets' perspective).

²⁵⁴ See, e.g., Jerry Stanton, *Comment, Lesson for the United States from Foreign Price Controls on Pharmaceuticals*, 16 CONN. J. INT'L L. 149, 165, 167 (2000). A variety of systems are used to control prices, such as reference pricing in Canada, price setting for government reimbursement such as in France, and caps on profit as is done in the U.K. Rosenfield, *supra* note 123, at 1052-53. Note, however, that certain sectors of the United States have negotiated pricing: for example, the Department of Veteran's Affairs program and state Medicaid programs negotiate price. See U.S. DEP'T OF HEALTH AND HUMAN SERVICES, *REPORT TO THE PRESIDENT: PRESCRIPTION DRUG COVERAGE, SPENDING, UTILIZATION, AND PRICES* 108, 101 (2000), <http://aspe.hhs.gov/health/reports/drugstudy/c3.pdf>. Note also that large purchasers, such as pharmaceutical benefits managers that cover millions of lives in the private sector, also negotiate price with pharmaceutical companies. *Id.* at 8-14

patent exclusivity period—to recoup costs broadly in these other markets. This keeps prices low in countries that practice this policy process.²⁵⁵

However, the implication of this international practice as compared with the US' lack of express and broad price controls or price negotiations results in an uneven distribution of costs. Although the world benefits from the research and development of important medicines that address the scourge of treatable illness, the significant costs attributable to its production are allocated to and paid for disproportionately by the US, where there are no price controls.²⁵⁶ This conclusion has been repeated by industry analysis and assessments for the European Commission.²⁵⁷

This international problem, then, is complex. Prices in the US are high because there are limited forces to keep them low. International price controls keep prices low in other countries, but fixed costs for developing drugs are high.

This international problem must have an international solution. Of course, countries devastated by disease such as HIV, AIDS, and malaria, cannot, and should not bankrupt their national health budgets and economies to promote drug development.²⁵⁸ However, industrialized countries must come together and address the spiraling costs of medicines.²⁵⁹ For at some point, the US will, or may, take the step of their international colleagues and implement price controls. At that point, it is likely that one or both results will occur: prices worldwide will escalate in an effort of brand name firms to recoup at least some of their costs; and/or research and development will be reduced.²⁶⁰ Even in the context of debates as to whether the pharmaceutical industry spends an inordinate amount on marketing and lobbying,

²⁵⁵ Rosenfield, *supra* note 123, at 1053.

²⁵⁶ See 150 CONG. REC. S4226, S4229 (daily ed. Apr. 24, 2004) (statement of Sen. McCain), available at 2004 WL 854311 (“The United States represents the largest pharmaceutical market in the world. Our taxpayers make substantial investments into pharmaceutical research and development. And yet, Americans are still paying 30 to 75 percent more for their prescriptions than consumers in Canada, the European Union, and elsewhere.”).

²⁵⁷ See ALFONSO GAMBARDELLA ET AL., GLOBAL COMPETITIVENESS IN PHARMACEUTICALS: A EUROPEAN PERSPECTIVE, at 44 (2000), available at http://europa.eu.int/comm/enterprise/library/enterprise-papers/pdf/enterprise_paper_01_2001.pdf (“[T]he relative position of the US as a locus of innovation has increased over the past decade compared to Europe.”); PHARM. RESEARCH & MFRS. OF AM., PHARMACY INDUSTRY PROFILE 2004, at 5 (2004), <http://www.trinity.edu/sbachrac/drugdesign/Drug%20Costs%20Articles/Phrma%202004%20review.pdf> (“The increased concentration of research efforts in the United States is reflected by the fact that 8 of the top 10 medicines by sales originate from the United States, compared to 2 from Europe.”).

²⁵⁸ See, e.g., Peter Benesh, *What to Do About Cheap Drug Imports? Coordinate*, INVESTOR'S BUS. DAILY, June 20, 2005, at A8, available at 2005 WLNR 9823068.

²⁵⁹ A step in this direction can be seen in the United States and Australian discussions for a trade agreement, which expressly, for the first time, discusses drug pricing and disparities thereof. See OFFICE OF THE U.S. TRADE REP., U.S.-AUSTRALIA FTA SUMMARY OF THE AGREEMENT (2004), http://www.ustr.gov/Trade_Agreements/Bilateral/Australia_FTA/US-Australia_FTA_Summary_of_the_Agreement.html (last visited Aug. 1, 2005). Commentators have agreed that such trade leverage should be used to address worldwide drug pricing issues. See Benesh *supra* note 263; Editorial, *Drug Trade*, WASH. POST, Jan. 13, 2004, at A20, available at 2005 WLNR 9618864.

²⁶⁰ Similar conclusions have been published in the U.S. Surgeon General's Report. See TASK FORCE, *supra* note 10. Note also that an analysis by the Department of Commerce of OECD countries has concluded that European price controls reduce pharmaceutical company returns and concomitantly, research and development expenditures. See U.S. DEP'T OF COMMERCE, PHARMACEUTICAL PRICE CONTROLS IN OECD COUNTRIES: IMPLICATIONS FOR U.S. CONSUMERS, PRICING, RESEARCH AND DEVELOPMENT, AND INNOVATION, at 12 (2004), available at <http://trade.gov/td/chemicals/drugpricingstudy.pdf>.

significant price reductions worldwide will clearly have at least some impact upon the development of new drugs.

Industrialized nations alone have tremendous power to negotiate price with all industries. If members of this group were to consider cooperating to determine equitable methods to allocate research and development costs across economies, there may be potential to avert a significant crisis in price shifting from the US to other countries and the potential slowing of drug development for future therapeutic and social benefit.

G-8 countries,²⁶¹ in cooperation with the WTO, may consider setting sliding scale pricing by country and aggregate objective income levels, and either mandating brand name firm's sell at these prices to WTO countries; or, if refused by brand name firms, allowing imported or country-based generics to produce needed drugs under an expanded public health exception based on the current Doha Declaration.²⁶² This would allow those countries with limited resources to have access to drugs without facing significant financial burdens of drug costs while trying to improve the quality of life of their citizens. As the health and the economies of these countries improve, the investment of pharmaceutical companies in supplying their products at lower prices will eventually benefit them once such countries can afford less-subsidized pricing.

An adjunct or alternate strategy is to consider sliding scale pricing within each country. Capping the highest prices by overall aggregate annual income and then further parsing price by income levels within countries may allow for those even in developed countries with limited resources to afford needed medicines. Public pricing programs that are based, for example, on multiples of the poverty level (including, for example, low or no cost drugs for those within, say, 200% of poverty) would provide access to citizens within these developed countries. Such a system would then result in more affordable pricing for those most in need. The US would be particularly apt for such a program due to its fragmented coverage of health care for its citizens, assuming no national health insurance or other encompassing national coverage is implemented for all its citizens in the interim.

Of course, such a regime will reduce pharmaceutical company profits, and indeed, may even reduce funds for research and development. In return for this concession, all countries should ensure that a robust patent regime is enforced if brand name firms choose to enter into a market, maintaining exclusivity for patent rights to the innovating brand name firm even in the face of lower, and in some cases, much lower prices. In that way, brand name firms would continue to receive income under sales in developed countries. As well, they would develop sales in less developed countries, which represent investments into improved health and economies resulting in higher returns in the future. Further, by temporizing and standardizing prices through this system, there would be less incentive for consumers to go to the Internet and other questionable sources for drug supply, and

²⁶¹ See THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 716 (Joseph Pickett, et al. eds., Houghton Mifflin Company 4th ed. 2000) (defining "G8" as the "countries of Canada, France, Germany, Italy, Japan, Russia, the United Kingdom, and the United States. Representatives from these countries meet to discuss economic concerns." G8 is the abbreviation for Group of Eight).

²⁶² See Press Release, World Trade Organization, Decision Removes Final Patent Obstacle to Cheap Drug Imports (Aug. 30, 2003), available at http://www.wto.org/english/news_e/pres03_e/pr350_e.htm (describing public health exception allowing countries to produce and import medicines without violating intellectual property rights of patent holders).

there would be significantly reduced incentive for counterfeit drug makers to enter into the market. In this manner, brand name firms would recoup a significant fraction of the losses associated with lost sales due to counterfeit drugs. And, more importantly, individuals would have access to lifesaving drugs without having to play Russian Roulette with counterfeits.

Of course, such a regime as described here is not the perfect solution; indeed, it is doubtful that there is a perfect solution, much as many would like. However, the potential importation of, and manufacture and sale of fake drugs exists because of high prices; and high prices exist in part due to high development costs and lack of price controls. Balancing these factors is difficult, but through international cooperation to reduce prices for those who need lifesaving drugs the most while maintaining at least some financial incentives for drug development in developed countries, more patients will obtain their needed medicines, brand name firms will have their intellectual property rights protected, and counterfeit sales will be reduced which will then inure to the legitimate drug producer.

VI. CONCLUSION

Counterfeits and importation are inextricably intertwined in the political sphere as well as the practical reality of the world's drug supply. It should be emphasized that the concerns regarding importation and vulnerability to counterfeit and tainted drugs are not focused upon legitimate suppliers, but instead upon those who peddle illicit fakes. Simply because a group of patients can take a bus up to Canada to a legitimate brick-and-mortar pharmacy and buy authentic medicines is not an argument for wholesale importation²⁶³ (and even bricks-and-mortar pharmacies in Canada, and their customers, as discussed above, have been subject to deadly fake medicines).²⁶⁴ The issue is not that it is *possible* to buy legitimate drugs in Canada or elsewhere; instead, the issue is that importation may open up the closed US system to counterfeits and result in patients buying and using those fakes, with their attendant negative consequences. Our own experience in this country, as well as extensive international experience, has shown the staggering ease by which these activities can be engaged, and the tragic harm that has accompanied it.

In the medical world, there is a standard saying: the chances may be 1 in 1000, but when it happens to you, it's 100%. This aphorism is particularly apt as applied to drug importation. Perhaps the chances are 1 in 1000 of a patient receiving a counterfeit drug each time he or she buys medications—the 3.5 billion times that happens in the US each year. Perhaps he or she is lucky the first, second, fifth, tenth, hundredth, five hundredth time he or she takes each pill, capsule, or administers an injectable. But when it is your son, your daughter, your spouse, your grandparent, your sibling, or your friend, if that counterfeit drug event strikes even once, no financial or legal remedy, even if the perpetrators could actually be brought to justice, could ever replace the time and life lost or the physical and emotional suffering experienced because of it. The 192,000 relatives of those killed in China each year due to counterfeits know this; the families of the 500 children who watched their children die because of fake antifreeze-laden cough syrup know

²⁶³ Ironically, legalizing importation could overwhelm the Canadian system, raise prices, and heighten risks of counterfeits during over the border "buying trips." See Finkelstein, *supra* note 73.

²⁶⁴ See *supra* notes 80, 115 (discussing Canadian counterfeit investigations).

this.²⁶⁵ This reality must be remembered when considering whether we, as a country, are willing to bet our lives, and the lives of our families and loved ones, on the notion that we can outsmart those who would prey upon the innocent, vulnerable patient. Because if we are wrong, by taking that imported drug, we may truly fade to black.²⁶⁶

²⁶⁵ Cockburn et al., *supra* note 14, at 302-303. *The Global Threat of Counterfeit Drugs*, *supra* note 14.

²⁶⁶ Fade to black is common slang for killing oneself. See Urban Dictionary, <http://www.urbandictionary.com> (enter “fade to black” in the “Search” box) (last visited Aug. 16, 2005) (“Popularized in the 80’s, as a term for suicide, by the band Metallica in the song ‘Fade To Black’.”). See, e.g., METALLICA, *Fade to Black*, on RIDE THE LIGHTNING (Elektra Records 1984):

Life it seems, will fade away
Drifting further every day
Getting lost within myself
Nothing matters no one else
I have lost the will to live
Simply nothing more to give
There is nothing more for me
Need the end to set me free
Things are not what they used to be
Missing one inside of me
Deathly lost, this can't be real
Cannot stand this hell I feel
Emptiness is filling me
To the point of agony
Growing darkness taking dawn
I was me, but now he's gone
No one but me can save myself, but it's too late
Now I can't think, think why I should even try
Yesterday seems as though it never existed
Death greets me warm, now I will just say good-bye