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A DOSE OF REALITY: PROMOTING ACCESS TO PHARMACEUTICALS

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Introduction

Abstract

The U.S. uses and benefits substantially from prescription drugs. Pharmaceuticals save lives, relieve suffering, and promote the quality of life for those with access to them. However, access means both availability of the authentic drug and access at prices patients can afford. Unfortunately, current public policy does not effectively address either component. The result is the worst of all worlds: neither goal is accomplished. Policymakers focusing on price fail to

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address safety, resulting in vulnerabilities that allow counterfeits and diverted drugs to enter into the supply chain; and those focusing on safety fail to address high prices, driving vulnerable patients to questionable and unsafe medication sources. A dose of reality that addresses these intertwined characteristics of access is proposed in this article. This work first reviews the key safety-price interface: the problem of counterfeit drugs here and abroad. It identifies critical root causes that allow such a market to emerge, including the high costs of researching, developing, and selling authentic drugs that create the prices that drive vulnerable patients to alternate sources. Further, it details the other key infrastructural issues: the low financial and social costs of manufacturing fakes, a porous and poorly regulated U.S. domestic gray market and international parallel trade system, the limited accountability of drug sales via the Internet, and the limited provider and patient suspicion of fake drugs. It then critically assesses the primary safety effort that ignores price—drug pedigree and track-and-trace systems, and the primary price effort that ignores safety—drug importation. It finds that, beyond ignoring the complementary facet of access, both have striking limitations in dealing with the problems they purport to address. Taking these analyses into consideration, this article presents a comprehensive legislative policy proposal that addresses both price and authenticity components of drug access, using extant private efforts and public expertise to promote efficient policy implementation. The resultant program has as its core a low cost/no cost drug program that segregates eligible patients from private markets. It also mandates both brand name and generic company participation as part of the social contract, requires identification and registration of legitimate wholesalers, bans Internet drug sales unless pharmacies are accredited by the National Association of Boards of Pharmacy, prohibits drug importation, directs the Centers for Disease Control and Prevention to create aggressive public and provider education on counterfeit drugs, and significantly increases penalties for counterfeiters to fit the crime of cheating the hopes of the sick and vulnerable.

I. INTRODUCTION

In the aggregate, the U.S. spends a tremendous amount on prescription drugs. In 2006, sales were $274.9 billion, an 8.3% increase from the previous year.[1] Prescriptions written for drugs rose

[1] IMS Health, *IMS Reports U.S. Prescription Sales Jump 8.3 Percent in 2006, to $274.9 billion*, Mar. 8, 2007, http://www.imshealth.com/ims/portal /front/articleC/ 0,2777,6599_3665_80415465,00.html (last visited Aug. 27, 2007).

4.2% in 2006 to an astounding 3.7 billion.[2] Moreover, spending is likely to continue to increase, with estimates that expenditures for medications will reach $446.2 billion by 2015[3]—or $1.2 billion dollars *a day*.

We spend this money, and physicians prescribe these drugs, for good reason. Pharmaceuticals represent a powerful tool in the arsenal of medicine. Prescription drugs save lives, relieve suffering, and promote the quality of life for those who have access to them.[4]

However, the latter phrase is important. The benefits of medications only redound to those with access to them. Access, in this context, means two things: access to the actual, effective drug; and access to the medication at a price patients can afford. Unfortunately, both of these related aspects of access are problematic,[5] and current public policy does not effectively address either.

Further, this policy failure has resulted in market entry of the worst of both characteristics of this access issue. Policymakers attempting to address one aspect of the issue—price—fail to address the issue of safety, resulting in vulnerabilities that allow unsafe, ineffective counterfeits and diverted drugs to enter into the supply

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[2] *See id.*; *see also* IMS Health, *Channel Distribution by U.S. Dispensed Prescriptions*, Mar. 2006, http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_80411817_80413655,00.html (last visited Aug. 27, 2007).

[3] *See* KAISER FAMILY FOUNDATION, PRESCRIPTION DRUG TRENDS 4 (2006), http://www.kff.org/ rxdrugs/upload/3057-05.pdf.

[4] *See, e.g.*, Frank R. Lichtenberg, *The Impact of New Drug Launches on Longevity: Evidence from Longitudinal Disease-Level Data from 52 Countries, 1982-2001*, 5 INT'L J. HEALTH CARE FIN. & ECON. 47 (2005) (reporting new cancer drugs accounted for majority of cancer survival gains); DAVID M. CUTLER, YOUR MONEY OR YOUR LIFE (2004) (noting medicine and medical care costs justify the benefits); B. R. Schackman et al., *Cost-effectiveness Implications of the Timing of Antiretroviral Therapy in HIV-infected Adults*, 22 ARCHIVES INTERNAL MED. 2478, 2482 (2002) (finding new medications reduced death rates associated with AIDS); Frank R. Lichtenberg, *Are the Benefits of Newer Drugs Worth Their Cost? Evidence from the 1996 MEPS*, 20(5) HEALTH AFFAIRS (MILWOOD) 241-51 (2001) (finding people consuming newer drugs were significantly less likely to die by the end of the survey and were significantly less likely to experience work-loss days, and that use of newer drugs tends to lower all types of nondrug medical spending, resulting in a substantial net reduction in the total cost of treatment); Samuel A. Bozette et al., *Expenditures for the Care of HIV-infected Patients in the Era of Highly Active Antiretroviral Therapy*, 344 NEW ENG. J. MED. 817, 822 (2001) (finding antiviral therapy for HIV patients cost-effective).

[5] Unfortunately, in the United States, 47 million patients lack health insurance, which reduces their ability to financially afford medications, and drives them toward high risk sources, putting them at risk for unsafe, fake, or diverted drugs. *See, e.g.*, CENTER ON BUDGET AND POLICY PRIORITIES, THE NUMBER OF UNINSURED AMERICANS IS AT AN ALL TIME HIGH (2007), http://www.cbpp.org/8-29-06health.htm (last visited Aug. 31, 2007).

chain. Other efforts, focusing on anti-counterfeiting and maintaining a strictly regulated supply chain to address the safety issue, do not address the problem of high price that keeps innovative medicines out of reach of vulnerable patients who need them most. Both are unrealistic as purported solutions to the problems they respectively try to address.

What is needed is a dose of reality focusing on both of these intertwined characteristics of access. This article attempts to provide such an approach. In Part II, it reviews the issue of counterfeit drugs in its many manifestations here and abroad. It finds the problem is considerable and growing. It concludes that opening the U.S. system to unfettered external drug supplies is an unsound public policy, particularly since it is the most price-sensitive, vulnerable patients who will bear the brunt of risk associated with counterfeits.

In Part III, this article turns to some of the root causes associated with the fertile black market of producing and selling counterfeit drugs. The issues of high costs for researching, developing, and selling authentic drugs, and the resultant high prices that drive vulnerable patients to unsafe sources, are reviewed. This Part also assesses the contributions of the low financial and social costs to manufacture fakes, the gray market and parallel trade, the Internet, and limited provider and patient suspicion, in creating the perfect storm that results in demand-and-supply-side dynamics allowing counterfeit sales and purchases to total in the billions of dollars each year.

Part IV reviews the key failed policies that focus on safety and price. Use of pedigree and track-and-trace technology focusing on safety has significant holes that prevent it from accomplishing its goal. Further, it does not address alternative sources that represent the market for the vulnerable displaced from the technologically shored up market, nor the challenges of access due to price. This Part also reviews the key policy strategy to improve price access: drug importation. It finds that importation is not only unlikely to attain its goal of cheaper prices, but it also ignores the realities of the infiltration of counterfeits in the foreign drug market, as well as the tattered and ineffective safety infrastructure of the F.D.A. in attempting to regulate foreign drug sources.

In Part V, a policy proposal is presented that attempts to promote both price and authentic drug access for those in need. The foundation of this proposal is the use of existing private infrastructures to create a low cost/no cost drug program, and to build upon this in coordination with extant government and community expertise to create national drug access—addressing both price and authenticity

aspects of that access. Finally, in Part VI, the article offers some concluding remarks.

II. THE PROBLEM OF COUNTERFEIT DRUGS

A. Types

When considering counterfeit drugs, many earlier detections focused upon drugs for conditions such as erectile dysfunction, resulting in little sympathy for these victims because of the lifestyle nature of these medicines.[6] However, this state of affairs has changed dramatically over the last several years. Recently detected counterfeits have included anti-arthritis drugs, antibiotics, antihistamines, anti-parasitic drugs, AIDS/HIV therapy, cancer drugs, cardiac drugs, cholesterol drugs, flu medications, hormone replacement therapy, insulin, over-the-counter pain medications, and many more.[7] The counterfeit market has now matured and, consequently, spans the spectrum from lifestyle drugs to lifesaving drugs.

The harm associated with counterfeit drugs generally occurs in four ways.[8] First, a fake drug may in reality be a different drug, resulting in a patient not being treated for a disease he or she has. This may occur, for example, when vials (sometimes purchased on online sites like Ebay[9]) are relabeled as another more expensive drug, such as a more expensive antibiotic. This antibiotic is likely to have different bacterial coverage than that prescribed for the patient, or it may be

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[6] *See, e.g.*, Ben Hirschler, *Criminals Make Killing from Fake Drugs*, REUTERS HEALTH, Aug. 1, 2005, *available at* http://www.ucsfhealth.org/childrens/health_library/reuters/2005/08/20050801 elin017.html (last visited Aug. 2, 2007) (describing the ubiquity of counterfeit 'lifestyle' drugs).

[7] *See* Robert Cockburn et al., *The Global Threat of Counterfeit Drugs: Why Industry and Governments Must Communicate the Dangers*, 2 PLOS MEDICINE 0302 (April 2005), *available at* http://medicine.plosjournals.org/archive/1549-1676/2/4/pdf/10.1371_journal.pmed.0020100-S.pdf; Associated Press, *Customs Agents Seize Counterfeit Tamiflu*, MSNBC.COM, Dec. 18, 2005, *available at* http://www.msnbc.msn.com/id/10523190 (last visited Oct. 29, 2007).

[8] *See* Bryan A. Liang, *Fade to Black: Importation and Counterfeit Drugs*, 32 AM. J.L. & MED. 279, 283 (2006).

[9] *See* LEW KONTNIK, PHARMACEUTICAL COUNTERFEITING: PREVENTING THE PERFECT CRIME 2 (2004), *available at* http://www.fffenterprises.com/FFF/Downloads/fff_wht_ppr_111804.pdf; *see also* GLOBALOPTIONS INC., AN ANALYSIS OF TERRORIST THREATS TO THE AMERICAN MEDICINE SUPPLY 29-30 (2003), http://www.globaloptions.com/booktext2003.pdf (noting that pharmaceutical manufacturing and labeling equipment is also available on Ebay). Ebay has been found to allow sales of counterfeit drugs such as steroids and Viagra. *See The £4billion Car Boot Sale*, NEWS & STAR (U.K.), Aug. 30, 2005, *available at* http://www.newsandstar.co.uk/familylife/viewarticle.aspx?id=277293 (last visited Aug. 3, 2007).

inactive due to drug expiration or poor storage conditions.[10] In this situation, not only is the patient left untreated for significant disease, there is also a mistaken clinical impression that there are resistant strains in the population because the first line therapies appear to be ineffective.[11] Stronger, second line therapies will be deployed, contributing to acceleration of pathogen resistance.[12] Sometimes a totally different category of drug is substituted. For example, patients who are prescribed drugs such as growth hormone for HIV treatment and other diseases have received dangerous substitutes including insulin and steroids, expertly labeled to be indistinguishable from the true drug.[13]

Another way counterfeits can manifest harm is through use of an incorrect concentration or dosage of the drug.[14] In this situation, the wrong dose may result in clinically dangerous situations. For example, with Botox®[15] treatments, a physician was supplied with a research formulation of Botox® when trying to obtain the drug for anti-wrinkle treatment—the former a much higher concentration formulation and not intended for human use.[16] It caused respiratory paralysis and nearly death for several patients including the physician who was using the drug on himself.[17] Similarly, a patient who ordered an erectile dysfunction drug online experienced the following:

> [I had a] throbbing headache and my face went bright red. … There was also the desired effect, but I felt so awful I had to sit in the bathroom until the headache

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[10] *See* Liang, *supra* note 8, at 283-284. *See also* Rick Roberts, *Counterfeit Biologics: A Personal Narrative*, 10(4) J. BIOLAW & BUS. 37 (2007) (describing an HIV patient's firsthand account of being a victim of fake biological drugs).

[11] *See* WORLD HEALTH ORG., FACT SHEET NO. 194: ANTIMICROBIAL RESISTANCE (2002), www.who.int/mediacentre/factsheets/fs194/en (last visited Aug. 2, 2007).

[12] *See id.*

[13] *See, e.g.*, Matthew Herper, *Bad Medicine*, FORBES, May 23, 2005, at 202, 204, *available at* http: //www.forbes.com/home_europe/free_forbes/2005/0523/202.html (last visited Aug. 2, 2007); *see also* Roberts, *supra* note 10 (describing fake growth hormone substituted with human chorionic gonadotropin, a female steroid).

[14] *See* Liang, *supra* note 8, at 284.

[15] Botox is the brand-name form of Botulinum Toxin Type A made by Allergan. It is used for temporary reduction of wrinkle appearance. *See* Mayo Clinic, *Botox: Is This Wrinkle Treatment for You?*, MAYOCLINIC.COM, Aug. 4, 2006, http://www.mayoclinic.com/print/botox/SN00040/METHOD=print (last visited Oct. 29, 2007).

[16] *See* Liang, *supra* note 8, at 284; *see also* Press Release, U.S. Dep't of Justice, Professor of Opthalmology/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 (describing the research Botox formulation case).

[17] *See* Liang, *supra* note 8, at 284.

> subsided [and a] few days later, I tried again and had a similar experience. This time I also felt nauseous.[18]

His physician determined that the counterfeit version he obtained had a much higher dose than the authentic drug.[19]

Rather than having an increased concentration, other patients have had their life-saving drugs diluted. For example, most cancer patients need the red blood cell promoting drug erythropoietin after chemotherapy.[20] Counterfeiters sold a form of this IV drug and diluted it with bacterially-contaminated water that was then purchased and injected into thousands of immunocompromised patients. The poisoning of the drugs in this way causes adverse reactions that go beyond patient sensitivity to even legitimate non-therapeutic materials in the medications, such as the excipients.[21]

Next, and highly disconcerting, are situations where counterfeiters manufacture fakes using toxic materials. These counterfeiters make the fake drug with no active ingredients, but rather with harmful ingredients in order to make the drug appear more realistic.[22] Patients taking these drugs are not only left untreated, but are also injured by the harmful materials used to make the counterfeit.

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[18] *See* Barney Calman, *As Counterfeit Medicines Reach Local Chemists, Are YOU At Risk?*, DAILY MAIL (U.K.), Oct. 22, 2007, *available at* http://www.dailymail.co .uk/pages/ live/articles/health/healthmain.html?in_article_id=489136&in_page_ id=1774 (describing experience of patient who bought fake drugs over the Internet and experienced an overdose of the drug).

[19] *Id.*

[20] Erythropoietin is a large biologic hormone that stimulates red blood cell growth and counteracts the anemia patients may experience with cancer and HIV treatment. *See, e.g.*, *Epo*, DRUG DIGEST, Aug. 2, 2002, http://www.drugdigest.org/DD/DVH /Uses/0,3915,234%7CEpo,00.html.

[21] *See* Thomas A. Wheatley, *What Are Excipients?*, *in* EXCIPIENT TOXICITY AND SAFETY 1 (Myra L. Weinger & Lois A. Kotkoskie eds., 1999) (differing excipients create risks for patient adverse reactions to medicines; the risks associated with fake drugs are even greater, since they do not use tested excipients); Liang, *supra* note 8, at 284, 290. *See, e.g.*, Michael J. Akers, *Excipient-Drug Interactions in Parenteral Formulations*, 91 J. PHARMACEUTICAL SCI. 2283 (2002); Paul Baldrick, *Pharmaceutical Excipient Development: The Need for Preclinical Guidance*, 32 REG. TOXICOLOGY & PHARMACOLOGY 210 (2000); Larry K. Golightly et al., *Pharmaceutical Excipients: Adverse Effects Associated with Inactive Ingredients in Drug Products (Part I)*, 3(1) MED. TOXICOLOGY ADVERSE DRUG EXPERIENCES 128 (1988); Giorgio Pifferi et al., *Quality and Functionality of Excipients*, 54 IL FARMACO 1 (1999); Y. L. Wong, *Adverse Effects of Pharmaceutical Excipients in Drug Therapy*, 22(1) ANN. ACAD. MED.—SING. 99, 100 (1993). The F.D.A. 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. *See* R. E. Osterberg & N. A. See, *Toxicity of Excipients—a Food and Drug Administration Perspective*, 22 INT'L J. TOXICOLOGY 377 (2003).

[22] *See* Liang, *supra* note 8, at 284.

For example, as noted above, counterfeiters have used bacteria-laced water, but in addition they have employed brick dust, rat poison,[23] boric acid (commonly used as a cockroach killer, it causes renal failure in humans), colored dye, floor wax, powdered cement, and toxic yellow road paint.[24] In a particularly shocking case that has unfortunately repeated itself, counterfeiters have used antifreeze in fake cough syrup, resulting in the death of hundreds of children before the counterfeit was detected.[25] Another outrageous case involves counterfeit cystic fibrosis inhalers for pediatric patients that were filled with bacterially contaminated materials. This substance, masquerading

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[23] *See* Calman, *supra* note 18 (reporting analysis showing brick dust and rat poison in counterfeits).

[24] *See* Liang, *supra* note 8, at 284.

[25] *See* Liang, *supra* note 8, at 284-85; *see also* Walt Bogdanich, *From China to Panama, a Trail of Poisoned Medicine*, N.Y. TIMES, May 6, 2007, *available at* http://www.nytimes.com/2007/05/06/world/ americas/06poison.html?ref=americas (outlining use of Chinese-sourced cough syrup using ethylene glycol); Statement by William K. Hubbard for the Coalition for a Stronger FDA, before the Subcomm. on Oversight & Investigations, Comm. on Energy & Commerce, U.S. House of Representatives (Nov. 1, 2007), *available at* http://energycommerce.house.gov/cmte_mtgs/110-oi-hrg.110107.Hubbard-Testimony.pdf, noting specific examples of dangers in the international drug market, including:

> [The] recent substitution of ethylene glycol (antifreeze) for pharmaceutical grade glycerin in an elixir that was linked to 46 deaths in Panama, as well as to other deaths in Nigeria, India, South Africa, and Argentina. Those cases were ominously reminiscent of a similar contamination in 1996 that was associated with the deaths of 85 children in Haiti. In both cases, the sources of the substitution were reported to be Chinese drug manufacturers, as was the diethylene glycol contamination of toothpaste that was found recently in many countries, including the United States.

Id. at 3-4. A report on the deaths associated with the Panama poisoning in 2006 has noted the death toll to be at least 174. *See* Walt Bogdanich, *Panama Releases Report on '06 Poisoning*, N.Y. TIMES, Feb. 14, 2008, *available at* http://www.nytimes.com/2008/02/14/world/americas/14panama.html?ex=1360731600& en=781aac6ff03be2a7&ei=5088&partner=rssnyt&emc=rss (last visited Feb. 14, 2008). 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 also* AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY, MEDICAL MANAGEMENT GUIDELINES FOR ETHYLENE GLYCOL, http://www.atsdr.cdc.gov/ MHMI/mmg96.html (last visited July 2, 2005).

as an authentic medication, was then sprayed directly in the children's vulnerable lungs.[26]

Finally, a means to pass off fakes that may involve all of the above is "salting." Salting occurs when fake drugs are mixed or "salted" with legitimate, authentic products or products with some active ingredient.[27] In this way, in the unlikely event patients, providers, or government inspectors attempt to detect counterfeits by assessing presence of active ingredient, fakes may avoid detection because a legitimate sample or counterfeit with some active ingredient is pulled for testing. It should be noted that simply because the counterfeit has some active pharmaceutical ingredient does not mean it will provide the desired clinical result.[28]

B. The U.S.

Counterfeit drugs in the U.S. are not new. Although the domestic drug supply has been relatively closed to counterfeits, the system has been infiltrated in the past by numerous breaks in the supply chain. For example, in a fascinating firsthand account, Greg

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[26] *See* Liang, *supra* note 8, at 285; *see also* Fox 35 News, *Attorney General Sues Tampa Couple Over Fake Cystic Fibrosis Drug*, http://www.wofl.com/_ezpost /data/14958.shtml (last visited Aug. 4, 2007).

[27] *See* Liang, *supra* note 8, at 285.

[28] *See id*. For example, during the counterfeit imported active pharmaceutical ingredient investigations in the early 1990s,

> [W]e found an instance, for example, in which a patient died because a finished carbamezapine drug, an anti-convulsant, did not work. Other patients who experienced seizures using the same product became seizure free once they used another carbamezapine product. The counterfeit carbamezapine API [active pharmaceutical ingredient], which was made with an imported counterfeit carbamezapine, met identification and potency testing requirements. The investigation determined the crystalline structure of the counterfeit altered the compression characteristics of the tablet which had an adverse effect on dissolution characteristics. Consequently, the tablet did not dissolve and the carbamezapine was not delivered to the target organ to manage the seizure disorder. It apparently just passed through the intestinal tract.

Statement of Carl R. Nielsen, Retired Former Dir. of the Office of Regulatory Affairs Div. of Import Operations & Policy, before the Subcomm. on Oversight & Investigations, Comm. on Energy & Commerce, U.S. House of Representatives 3-4, (Nov. 1, 2007), *available at* http://energycommerce. house.gov/cmte_mtgs/110-oi-hrg.110107.Nielsen-Testimony.pdf.

Schulte, a Supervisory Special Agent of U.S. Immigration and Customs Enforcement in the Department of Homeland Security, has provided some examples spanning decades within his personal experience.[29] From Laetrile Clinics operating over the Mexican border (which counted patients such as the late Coretta Scott King[30]) that began in the 1970s, through substandard steroids with fake labels promulgated by a former Olympic athlete acting with fugitives to distribute the fakes throughout the U.S. in the 1980s,[31] to large scale Tagamet®[32] counterfeiting by a former pharmacist detected in the late 1980s whose drugs were, for the most part, never recovered,[33] there have been many examples of counterfeits and drug scams affecting American citizens over the past several decades.

Schulte indicates that this problem has continued throughout the 1990s and into today.[34] For example, U.S. Customs in 1997 seized

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[29] *See* Greg Schulte, *An Overview of Pharmaceutical Smuggling Cases in San Diego: It Goes Better When Agencies Work Together*, 9(4) J. BIOLAW & BUS. 41 (2006).
[30] *See id.*
[31] *See id.* at 42.
[32] Tagamet® is the brand name form of cimetidine, produced by GlaxoSmithKline. It is a drug used for gastric disease. *See* TAGAMET, http://www.drugs.com/pdr /tagamet.html (last visited Aug. 27, 2007).
[33] Schulte, *supra* note 29, at 41-42; *see also infra* note 187 (describing a counterfeit case where 90% of the fakes were never recovered, potentially impacting 25,000 patients).
[34] For example, some pharmacists are currently engaging in highly risky activities by illegally importing drugs from high-risk countries like China. *See Colorado Pharmacy Indicted for Illegal Importation*, DRUG TOPICS, Sept. 4, 2007, http://www.drugtopics.com/drugtopics/article/articleDetail.jsp?ts=091207093618& id=453853 (last visited Sept. 8, 2007) (reporting Colorado pharmacist's indictment for importing human growth hormone from China, repackaging it with U.S. pharmacy name, and selling it to patients); *Chinese Counterfeit Medicines Pose Danger To Houston*, CLICK2HOUSTON.COM, Jan. 10, 2008, *available at* http://www.click2houston.com/investigates/ 15015623/detail.html (last visited Jan. 10, 2008) (outlining cases of counterfeit drugs imported from China to be sold in pharmacies). China is a particularly worrisome source of drugs because there is limited Chinese regulation of chemical companies that sell pharmaceutical ingredients, despite its reputation for producing counterfeit drugs and China's awareness of the problem since at least the mid-1990s. *See, e.g.*, Bogdanich, *supra* note 25; *see also* GOV'T ACCOUNTABILITY OFFICE, DRUG SAFETY: PRELIMINARY FINDINGS SUGGEST WEAKNESSES IN F.D.A.'S PROGRAM FOR INSPECTING FOREIGN DRUG MANUFACTURERS 10 (2007), GAO-08-224T, *available at* http://energy commerce.house.gov/ cmte_mtgs/110-oi-hrg.110107.Crosse-Testimony.pdf. Indeed, these manufacturers travel to international trade shows to openly advertise their products. Advertising manufacturers include manufacturers accused by U.S. authorities of supplying steroids to illegal underground labs, another whose representative was arrested in 2006 for patent violations, and exporters, owned by the Chinese government itself, which sold poison mislabeled as a drug ingredient, killing 200 people and harming others in Haiti and Panama. *See id.* Another Chinese company's representative could not attend the trade shows because he was

controlled substances manufactured in India that were intended for illegal sale to U.S. citizens by passing them through Mexico and Free Trade Zones as a transit site.[35] Customs also thwarted the attempted smuggling of Mexican pharmaceuticals for use in high-end Utah pharmacies in 1998,[36] and investigated the use of over-the-border medications by a U.S. physician for U.S. patients in 1999 that resulted in a patient's death.[37] In a more modern twist, Schulte also describes the seizure in 2004 of materials from India, discovered in a San Diego warehouse, that could produce $40 million in counterfeit Viagra®,[38] other drugs including the withdrawn Vioxx®,[39] as well as a host of other medications.[40]

Such U.S. experience is simply the tip of the iceberg. It would appear that counterfeit drug problems domestically are becoming more apparent and/or more systemic.[41] For example, the Department of

in a Houston jail on charges of selling counterfeit drugs covering the gamut of disease states: schizophrenia, prostate cancer, blood clots, Alzheimer's disease, and others. *See id.* Because of limited regulation, "there is little to stop them from exporting unapproved, adulterated, or counterfeit ingredients. The substandard formulations made from those ingredients often end up in pharmacies in developing countries and for sale on the Internet, where more Americans are turning for cheap medicine." *See id.*; *see also* Omario Kanji, *Paper Dragon: Inadequate Protection of Intellectual Property Rights in China*, 27 MICH. J. INT'L L. 1261, 1267-68 (2006) (discussing China as a primary source of fatal counterfeit drug products).

[35] *See* Schulte, *supra* note 29, at 42.

[36] *See id.* at 42-43.

[37] *See id.* at 43.

[38] Viagra® is the brand name form of sidenafil citrate, an erectile dysfunction drug produced by Pfizer. *See* VIAGRA, http://www.drugs.com/cdi/viagra.html (last visited Aug. 27, 2007).

[39] Vioxx® is the brand name form of rofecoxib, an anti-inflammatory agent that was withdrawn by Merck after safety concerns were raised. *See* VIOXX, http://www.drugs.com/search.php?searchterm =Vioxx&is_main_search=1 (last visited Aug. 27, 2007).

[40] *See* Schulte, *supra* note 29, at 43.

[41] Media investigations have also found serious issues of counterfeit drugs. *See, e.g.*, Karen Hansel, *"Bad Medicine": An I-Team Investigation, Part 2*, WISH-TV.COM, *available at* http://www.wishtv.com/Global/ story.asp?S=7305418&nav=menu35_2 (describing Indiana drug purchasing program that used F.D.A.-noted problematic Internet pharmacy and showed "package after package of counterfeit drugs … [coming] from China, India, Canada, all headed to the United States [with] …F.D.A. officials say[ing] they're concerned drugs found in the packages could be sugar pills, could have strictnine [sic] or ground up concrete, which was found in some tablets."); Chris Hansen, *Inside the World of Counterfeit Drugs*, NBC DATELINE (June 4, 2006) (describing counterfeit drug dilution case and broader problem of counterfeit drugs in the U.S.). The website that was mentioned in the in the Indiana program is suing the television station owner for defamation. *See* Joe Schneider, *Lin TV Sued for Defamation by Canadian Drug Company Over Report*, BLOOMBERG.COM, Nov. 20, 2007, *available at* http://www.bloomberg.com/apps/ news?pid=20601082&sid=aj_LbYrbdvLw&refer=canada (last visited Nov. 22,

Homeland Security has reported that the value of fake and contraband pharmaceuticals seized in the first half of 2007 rose by a factor of seven over the same period in 2006.[42] In addition, in August 2007, a federal grand jury indicted eighteen people for illegally selling fake drugs over the Internet, but not before they sold at least $126 million worth to consumers across the U.S.[43]

This is consistent with other large scale counterfeiting discoveries. Senator Charles Schumer in 2004 estimated that in New York alone, there had been nearly 100,000 instances of fake drugs used to fill drug prescriptions.[44] In 2003, more than 18 million doses of Lipitor®,[45] the world's best selling drug,[46] were recalled because of fake versions detected in the U.S. drug supply.[47] In that same year, the U.S. Food and Drug Administration ("F.D.A."), during blitz inspections of foreign drug imports at U.S. international mail facilities, found that 88% were unapproved, may have been stored

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2007); *see also infra* note 150 (discussing ease by which media obtained parallel trade license and contracting with known counterfeiter of drugs); *infra* notes 95 & 150 (discussing *London Times* undercover counterfeit investigation).

[42] *See* DEP'T OF HOMELAND SECURITY, U.S. CUSTOMS & BORDER PROTECTION, & U.S. IMMIGRATION & CUSTOMS ENFORCEMENT, MID-YEAR FY 2007–TOP IPR COMMODITIES SEIZED (2007), *available at* http://www.cbp.gov/linkhandler/cgov/import/commercial_enforcement/ipr/seizure/ 07_midyr_seizures.ctt/07_midyr_seizures.pdf; *see also Londonderry Firm Shipped Fake Cialis*, UNIONLEADER.COM, Sept. 5, 2007, *available at* http://www.unionleader.com/article.aspx?headline=Londonderry+firm+shipped+bogus+Cialis&articleId=42bdd1c8-ec5a-4c23-94e2-9d1a76cc53e3 (describing illegal U.S.-India effort to ship and sell counterfeit Cialis® in U.S.).

[43] *See* Greg Moran, *18 Indicted in Internet Pharmacy Operation*, SAN DIEGO UNION-TRIB., Aug. 3, 2007, *available at* http://www.signonsandiego.com/news/metro/20070803-9999-1m3pharm.html.

[44] *See* Press Release, Senator Charles E. Schumer, Schumer Reveals: Millions of NY'ers at Risk as Gaping Holes in Rx Regulations Allow Criminals to Introduce Counterfeits into Drug Supply Chain (Aug. 7, 2005), http://www.senate.gov/~schumer/SchumerWebsite/pressroom/press_releases/2005/PR41799.NYC%20Counterfeit%20Drugs.080705.html.

[45] Lipitor® is the brand name form of atovastatin, a cholesterol lowering drug produced by Pfizer. *See* LIPITOR, http://www.drugs.com/lipitor.html (last visited Aug. 27, 2007).

[46] *See, e.g.*, Julie Schmit, *Lipitor Sales on Track to Hit Record Despite Arrival of Generic*, USA TODAY, July 20, 2006, at Money 4B, *available at* http://www.usatoday.com/money/industries/health/drugs/ 2006-07-20-pfizer-usat_x.htm.

[47] *See* John Theriault, *Counterfeit Pharmaceuticals: Understanding the Threat*, 9(4) J. BIOLAW & BUS. 46, 48-49 (2006). In fact, these were a mixture of fake drugs made in Central America intermingled with South American versions of the actual drug. *See* Liang, *supra* note 8, at 281.

inappropriately, and most importantly, violated U.S. safety standards.[48]

Further, in 2004, the F.D.A. discovered fake drugs being imported by U.S. citizens over the Mexican border,[49] and in 2005 warned that fake Lipitor®, Viagra®, and an unapproved osteoporosis drug were being imported by U.S. citizens again over the Mexican border.[50] Mexican fakes are of great concern because of the extensive amount of drugs purchased there by U.S. citizens;[51] because of its status as a major source of counterfeits;[52] and because the World Health Organization ("W.H.O.") estimates that 40% of Mexican drugs are fake or tainted.[53]

C. International

Counterfeit medicines are only recently becoming an increasingly visible problem in the U.S.,[54] but they are a well-known

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[48] U.S. DEP'T. OF HEALTH & HUMAN SERVS., HHS TASK FORCE ON DRUG IMPORTATION: REPORT ON PRESCRIPTION DRUG IMPORTATION 13 (2004), *available at* http://www.hhs.gov/importtaskforce/Report1220.pdf.

[49] Press Release, U.S. F.D.A., F.D.A. Warns Consumers About Counterfeit Drugs Purchased in Mexico (July 30, 2004), http://www.fda.gov/bbs/topics/ANSWERS/2004/ANS01303.html.

[50] *Id.* Note, however, the recent discoveries of poor quality goods from China, from toothpaste to toys, being imported to these shores. *See, e.g.*, Emre Parker, *China Food Safety Woes Show U.S. Vulnerability*, MARKETWATCH, Aug. 29, 2007, http://www.marketwatch.com/news/story/china-food-safety-woes-show/story.aspx?guid=%7B44865B2E-749F-4226-BEDE-A7EE854446F9%7D. Indeed, like drugs, of which the F.D.A. inspects only 1%, Hubbard, *supra* note 25, at 6, the F.D.A. also inspects very few food imports—again 1% by its own estimates, *see* Parker, *supra*, and offending poor-quality and toxic foods come from similar sources: China, but, in fact, more frequently from Mexico and India. *See id.*

[51] One estimate is that U.S. citizens spend at least $800 million annually on drug purchases from Mexico. *See* Marv Shepherd, *Drug Quality, Safety Issues and Threats of Drug Importation*, 36 CAL. W. INT'L L.J. 77, 80 (2005) [hereinafter Shepherd, *Drug Quality*]; *see also infra* note 115 and accompanying text (describing seniors who go over the border to Mexico to purchase their drugs).

[52] *See* Parker, *supra* note 50; Amy M. Bunker, *Deadly Dose: Counterfeit Pharmaceuticals, Intellectual Property, and Human Health*, 89(6) J. PAT. & TRADEMARK OFF. SOC'Y 493, 501 (2007).

[53] *See, e.g.*, WORLD HEALTH ORG., REPORT OF THE PRE-ELEVENTH ICDRA SATELLITE WORKSHOP ON COUNTERFEIT DRUGS, 13 AND 14 FEBRUARY 2004, MADRID, SPAIN 12 (2004), http://www.who.int/medicines/services/counterfeit/Pre_ICDRA_Conf_Madrid_Feb2004.pdf.

[54] *See, e.g.*, Don Oldenburg, *Raising the Alarm on Counterfeit Drugs*, WASH. POST, Apr. 5, 2005, at C9 ("When people [in the U.S.] 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.") (quoting Darren Pogoda, Staff Attorney, International Anti-Counterfeiting Coalition).

phenomenon in the rest of the world.[55] This is of great concern to the U.S., as citizens here sometimes go to other countries or to questionable sources to obtain their medications,[56] and because policymakers have repeatedly attempted to allow importation of drugs into this country.[57]

It is not simply third-world countries that have experienced the scourge of counterfeit drugs, although they, and second-world countries, have been subject to tremendous abuse by those who would peddle fakes.[58] The European Union ("E.U.") has also had tremendous difficulties with counterfeit drugs infiltrating the drug supply. Numerous examples of such problems exist across Europe. For example, E.U. seizures of counterfeit medicines in 2006 increased 384% from 2005.[59] Further, in the first half of 2007 alone, five Class I

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[55] *See* Bryan A. Liang, *Parallel Trade in Pharmaceuticals: Injecting the Counterfeit Element into the Public Health*, 31 N.C. J. INT'L L. & COM. REG. 847, 850 n.5 (2006); ORGANISATION OF ECONOMIC AND COMMUNITY DEVELOPMENT, THE ECONOMIC IMPACT OF COUNTERFEITING AND PIRACY, PART I: OVERALL ASSESSMENT (2007), http://www.oecd.org/dataoecd/36/36/39543399.pdf (discussing worldwide prevalence of counterfeits, including counterfeit medicines).

[56] U.S. citizens may be placing themselves directly in harm's way by traveling to countries that have a high level of counterfeits. For example, there is a growing trend of Americans and others obtaining health care in India; *see, e.g.*, *Westerners Seek Cheap Medical Care in Asia*, USA TODAY, Sept. 24, 2005, *available at* http://www.usatoday.com/news/health/2005-09-24-asia-health_x.htm. This is of tremendous importance from a policy perspective because India has been identified as one of the primary sources of counterfeit drugs by the European Commission, followed by the United Arab Emirates and China. *See* Khomba Singh & Gireesh Chandra Prasad, *India Hub of Counterfeit Drugs: EC*, ECON. TIMES (India), June 23, 2007, *available at* http://economictimes.indiatimes.com/News/News_By_Industry/Healthcare__Biotech/Pharmaceuticals/India_hub_of_counterfeit_drugs_EC/articleshow/2142855.cms; *see also supra* notes 49-53 and accompanying text (describing U.S. citizens going to Mexico to purchase drugs and high percentage of fakes); *supra* note 51 (providing estimate that U.S. citizens spend $800 million annually on drugs from Mexico).

[57] *See infra* notes 240-290 and accompanying text (criticizing current importation efforts); Doug Trapp, *Spending Bills Would Allow Drug Importation*, AM. MED. NEWS, Aug. 27, 2007, *available at* http://www.ama-assn.org/amednews /2007/08/27 /gvsc0827.htm (describing 110th Congress bill provisions that would permit drug importation); *see also* Pharmaceutical Market Access and Drug Safety Act, S. 334, 109th Cong. (2005); H.R. REP. NO. 108-231 (2004), (Pharmaceutical Market Access Act of 2003; proposals that would allow drug importation); Liang, *supra* note 8, at 298-307 (criticizing, section by section, the leading importation bill, S. 334).

[58] *See, e.g.*, WORLD HEALTH ORG., COUNTERFEIT MEDICINES (2006), http://www.who. int.mediacentre/factsheets/fs275/en/index.html (describing counterfeit medicine harm and deaths in Argentina, Niger, Haiti, India, Peru, Russia, Dominican Republic, El Salvador, Indonesia, Kenya, Angola, Colombia, Lebanon, Mexico, Nigeria, Phillipines, Cambodia, and China).

[59] *See* EUROPEAN COMM'N, TAXATION AND CUSTOMS UNION, SUMMARY OF COMMUNITY CUSTOMS ACTIVITIES ON COUNTERFEIT AND PIRACY (2007),

recalls associated with fake drugs have occurred in the U.K.,[60] which has stringent regulations similar to those of the U.S.[61]

In 2006, the U.K. Medicines and Healthcare Products Regulatory Agency, working with local police, seized counterfeit Cialis® and Viagra® in East London which was slated for that country's domestic sales.[62] In 2005, the Agency discovered fake Lipitor® being sold,[63] and in 2004, it apprehended a manufacturer of fake Viagra®, capable of producing half a million fakes daily, that had already sold these products across Europe.[64] Other discoveries

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http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics/counterf_comm_2006_en.pdf.

[60] *See, e.g.*, U.K. MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY [U.K. M.H.R.A.], COUNTERFEIT MEDICINES AND DEVICES, http://www.mhra.gov.uk/home/idcplg?IdcService= SS_GET_PAGE&nodeId=252 (last visited Nov. 26, 2007); *see also* Calman, *supra* note 18 (outlining experience of counterfeit purchaser in U.K., how counterfeiters use same packaging equipment as legitimate producers, analysis showing brick dust and rat poison in counterfeits, use of Internet, and reporting W.H.O. estimate that up to 50% of drugs purchased online are fakes, while brick-and-mortar pharmacies also distribute fake medicines). Because of the increasing presence of counterfeit drugs in the U.K., the M.H.R.A. has established a strategic plan to address the issues; *see* U.K. M.H.R.A., *supra*; Anna Lewcock, *MHRA Launches New Action Plan to Combat UK Counterfeit Hub*, IN-PHARMA TECHNOLOGIST.COM, Nov. 26, 2007, http://www.in-pharmatechnologist.com/news/ng.asp?n=81623-mhra-counterfeit-drug-fakes-who (outlining U.K. counterfeit drug issues and M.H.R.A. three year action plan to address them).

[61] *See, e.g.*, U.K. M.H.R.A., HOW WE REGULATE (2007), http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=26 (last visited Aug. 18, 2007). Unfortunately, these regulatory systems are highly porous. Indeed, an owner of a Chinese company accused of illegally selling counterfeit drugs sold his drugs through an Internet pharmacy and also penetrated the highly regulated supply chain of legitimate distributors in the E.U., according to a U.S. customs official. *See* Bogdanich, *supra* note 25. This circumstance is relatively unsurprising when noting that, for example, the U.K.'s M.H.R.A. examines only 2,000 to 2,500 packs of medicine annually. *See* Jim Thomson, *How Effective is the U.K.'s M.H.R.A. at Protecting Patients?*, PHARMA MARKETLETTER, Oct. 22, 2007.

[62] *See* Press Release: Drugs Seized from a Flat in East London, U.K. M.H.R.A., *available at* http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&useSecondary=true&ssDocName=CON2023394&ssTargetNodeId=389 (last visited Aug. 28, 2007).

[63] *See* Press Release: Drug Alert, Ian Holloway, U.K. M.H.R.A., July 28, 2005, *available at* http://www.info.doh.gov.uk/doh/embroadcast.nsf/fd1653b6e6be59d180256b7900507749/fa895cc99606f5ee8025704c0050e887?OpenDocument (last visited Aug. 1, 2007); Sam Lister, *Heart Pills Taken by Millions Recalled as Fakes are Found*, THE TIMES (London), July 29, 2005, at 2, *available at* http://www.timesonline.co.uk/tol/news/uk/article549317.ece (reporting the statements of Nimo Ahmed, Head of Intelligence at the M.H.R.A., indicating that the discovery of the counterfeit drugs, originating outside of the E.U., demonstrated that counterfeit medicines could get into any supply chain, even the U.K.'s).

[64] *See* Sam Lister, *The £6m Secret Factory that Churned out Thousands of Fake Viagra Tablets*, THE TIMES (London), Nov. 27, 2004, at 1, 24, *available at*

included additional counterfeit Cialis®[65] and Reductil®[66] that same year.[67]

Of course, it is not only the U.K. that has been hit with counterfeit drugs. For example, it has been reported that, in 2006, there were 2.7 million fake medicines discovered within the E.U.—an almost 400% increase from the year before.[68] Spanish authorities raided counterfeit drug producers in 2005, seizing 30 million doses and ten tons of fake steroids, hormones, and cancer drugs, from a facility capable of producing 20,000 fake doses per hour; wholesalers in the Netherlands sold counterfeits inadvertently in 2004; German authorities raided a major wholesaler producing counterfeit AIDS drugs; Italian pharmaceutical traders distributed fake gastrointestinal

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http://www.groupsrv.com/science/viewtopic. php?p=535168 (last visited Aug. 2, 2007).

[65] Cialis® is the brand name form of tadalafil, an erectile dysfunction drug made by Eli Lilly. *See* CIALIS, http://www.drugs.com/pdr/cialis.html (last visited Aug. 28, 2007).

[66] Reductil® is the brand name form of sibutramine in the U.K., known as Meridia® in the U.S., and is an anti-obesity drug made by Abbott Laboratories. *See* MERIDIA, http://www.nlm.nih.gov/ medlineplus/druginfo/medmaster/a601110.html (last visited Aug. 28, 2007); REDUCTIL, http://www.3dchem.com/moremolecules.asp?ID =350&othername=Reductil (last visited Aug. 28, 2007).

[67] *See* Press Release: Drug Alert: Class 2 Medicines Recall, G. P. Matthews, U.K. M.H.R.A., Aug. 23, 2004, *available at* http://www.info.doh.gov.uk/doh/ embroadcast.nsf/vwDiscussionAll/B20A3094D975C9B180256EFA00338EE1? OpenDocument (Cialis) (last visited Aug. 1, 2007); Press Release: Drug Alert: Class 2 Medicines Recall, G. P. Matthews, U.K. M.H.R.A., Sept. 2, 2004, *available at* http://www.info.doh.gov.uk/doh/embroadcast.nsf/fd1653b6e6be59d180256b790050 7749/ef724a067dc940a680256f03004e9df0?OpenDocument (Reductil) (last visited Aug. 1, 2007).

[68] *See, e.g.*, *supra* note 59, at 10; Melanie Abbott, *Europe's Concern over Fake Pills*, BBC NEWS, Sept. 6, 2007, *available at* http://news.bbc.co.uk/1/hi/programmes/ crossing_continents/6980432.stm (last visited Sept. 6, 2007); *see also* Eilish O'Regan, *Medicines Recalled as Counterfeits Still a Threat*, THE INDEPENDENT (Ireland), Nov. 28, 2007, *available at* http://www. independent.ie/national-news/ medicines-recalled-as--counterfeits-still-a-threat-1231898.html (last visited Nov. 30, 2007) (noting "[t]he focus on the threat posed by counterfeit medicines was maintained during 2006 and the IMB [Irish Medicines Board] contributed to the efforts of the Council of Europe and the World Health Organi[z]ation towards the development of anti-counterfeiting strategies" (quoting IMB Chief Executive Pat O'Mahoney)).

drugs in 1998;[69] and fake Zantac®[70] was discovered in Greece in 1994.[71]

The story is the same around the world. In addition to some of the countries specifically noted by the World Health Organization,[72] African countries have been tremendously impacted by fake medicines.[73] So, too, have Asian countries in the Mekong delta, as well as developed Asian countries such as Taiwan[74] and Australia.[75]

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[69] *See* PARTNERSHIP FOR SAFE MEDICINES, COUNTERFEIT DRUGS IN EUROPE FACT SHEET (2005), *available at* http://www.safemedicines.org/resources/europe.pdf.

[70] Zantac® is the brand name form of ranitidine, a stomach acid-reducing drug produced by GlaxoSmithKline. *See* ZANTAC, http://www.drugs.com/zantac.html (last visited Aug. 28, 2007).

[71] *See* GRAHAM SATCHWELL, A SICK BUSINESS 49 (2004). Satchwell also notes that developed countries such as Ireland also have problems with counterfeit drugs. *See, e.g.*, Anne-Marie Walsh, *Expert: Fake Drugs Flooding Market*, THE INDEPENDENT (Ireland), Oct. 27, 2007, *available at* http://www. independent.ie/national-news/expert-fake-drugs-flooding-market-1206185.html (quoting Graham Satchwell's remarks indicating that fake drugs were being sold in Ireland as part of the legitimate supply chain).

[72] *See* WORLD HEALTH ORG., *supra* note 58.

[73] *See, e.g.*, Roger Bate, *Fake!*, THE AMERICAN, Sept./Oct. 2007, *available at* http://american.com/ archive/2007/september-october-magazine-contents/ counterfeits-kill (describing the extent of fake drugs in Africa, including a recent study indicating 90% of malaria drugs are fake, contributing to the malaria parasite's drug resistance) (last visited Oct. 24, 2007); Phoung Tran, *Counterfeit Drug Sales in Africa Strong, Threaten Public Health*, VOICE OF AMERICA, Oct. 19, 2007, *available at* http://www.voanews.com/ english/2007-10-19-voa8.cfm (outlining Africa's significant problem of fake drugs and the problem's contribution to drug resistance) (last visited Oct. 24, 2007); Paul N. Newton et al., *Manslaughter by Fake Artesunate in Asia—Will Africa Be Next?*, 3 PLOS MEDICINE e197, June 13, 2006, *available at* http://medicine.plosjournals.org/perlserv/?request=get-document&doi =10.1371/ journal.pmed.0030197 (outlining problems in Asia caused by fake artenusate, a component of antimalarial drugs, similar to problems faced by Africa) (last visited Nov. 3, 2007).

[74] Bryan A. Liang, *Structurally Sophisticated or Lamentably Limited? Mechanisms to Ensure Safety of the Medicine Supply*, 16 ALB. L.J. SCI. & TECH. 483, 490-91 (2006); *see also* Angelica Oung, *DOH Issues Fake Drug Warning*, TAIPEI TIMES, Dec. 18, 2007, *available at* http://www.taipeitimes.com/News/taiwan/archives/ 2007/12/18/2003392998 (outlining examples of counterfeit drugs from China entering Taiwan).

[75] *See, e.g., Pan Can't Pay $3m Fine, Liquidator*, SYDNEY MORNING HERALD, Dec. 13, 2005, *available at* www.smh.com.au/news/National/Pan-fined-3m-over-counterfeit-drugs/2005/12/13/ 1134236045453.html (Pan Pharmaceuticals of Australia fined $3 million for supplying counterfeit drugs, now in receivership and unable to pay fines) (last visited Aug. 12, 2007).

D. Unsavory Elements

The lucrative nature of counterfeit drug sales has attracted tremendous numbers and types of unsavory elements. Counterfeiters have entered the market and achieved significant success before detection and apprehension.[76] The scope of participants covers a wide spectrum, from individuals looking to make quick cash to groups supporting organized crime and terrorist activities.

Mark Kolowich, one such individual, set up an Internet site selling fake drugs and profited "much more" than the government's $7 million dollar estimate.[77] His operations spanned the U.S. and the E.U.,[78] and ultimately created a supply network that included China, India, and Mexico.[79]

Other individuals, including those on the other side of the pond, have also made great profits from counterfeit drugs. Allen Valentine, a U.K. counterfeiter who was arrested just after making a *cash* offer of £1.25 million on a "palatial mansion," ran one of the largest counterfeit operations in Europe.[80] His Internet-based sales reached all over the E.U.[81]

Because of the lower risk[82] and high profit margins associated with fake licit drugs compared with illicit drugs such as cocaine and heroin,[83] counterfeit drug "entrepreneurs,"[84] have been joined by convicted former illicit drug dealers in the counterfeit market. For example, convicted cocaine traffickers Domingo Gonzalez and Julio Cruz created a counterfeit drug importation business, peddling at least

[76] Of course, we only know about counterfeiters who have been apprehended; given the vast numbers of email spam advertising drugs, it is likely that a large percentage of counterfeiters are never caught.

[77] *See* Liang, *supra* note 55, at 863. Further, Kolowich created a credit-card processing business to launder the profits and expanded operations to the Bahamas. *See* Heather Won Tesoriero, *Tangled Web: For Entrepreneur, Online Drug Sales Meant Fast Profits*, WALL ST. J., Aug. 30, 2005, at A1.

[78] *See* Won Tesoriero, *supra* note 77, at A1.

[79] Bryan A. Liang, *Crime, Terrorism, and Counterfeit Drugs: Addressing the International Regime*, 9(4) J. BIOLAW & BUS. 36, 37 (2006).

[80] *See Bogus Viagra Doctor Is Jailed*, BBC NEWS, Nov. 19, 2004, http://news.bbc.co.uk/2/hi/ uk_news/england/london/4027033.stm (last visited Aug. 28, 2007).

[81] *Id.*

[82] These activities are deemed "safer" than illicit drug sales. *See* Sally Kestin & Bob LaMedola, *Former Convicts Try a Safer Venture: Pharmaceuticals*, SOUTH FLORIDA SUN-SENTINEL, May 26, 2003, *available at* http://www.sun-sentinel.com/news/opinion/editorial/search/sfl-drugplayers26may26.story (last visited July 12, 2007).

[83] *See* Susannah Patton, *Cracks in the Pharmaceutical Supply Chain*, CIO ONLINE, Jan. 15, 2006, http://www.cio.com/article/16565/Cracks_in_the_Pharmaceutical_Supply_Chain (last visited Feb. 1, 2008).

[84] Mark Kolowich was described by the *Wall Street Journal* as an "entrepreneur" in relation to his illegal drug activities. *See* Tesoriero, *supra* note 78.

four million fake cholesterol tablets, and generating more than $10 million in drug sales in the U.S. before they were caught.[85] They came up with this scheme while in federal prison.[86]

In a more worrisome trend, organized crime syndicates and terrorist organizations have entered into the counterfeit drug market.[87] Indeed, in a September 2007 sting operation, U.S. officials, working with authorities from Mexico, Canada, China, Belgium, Australia, Germany, Denmark, Sweden, and Thailand, arrested 124 people operating a twenty-seven state criminal ring selling steroids and human growth hormone. The counterfeit drugs were made up of illegal substances supplied by up to thirty-seven chemical manufacturers in China.[88] In March 2006, the federal Joint Terrorism Task Force unsealed an indictment charging nineteen people with operating a global crime and terrorism ring, whose profits were being transferred to the terrorist group Hezbollah.[89] Unfortunately, the sale of fake drugs has previously supported terrorist activities.[90]

Similar observations have been made around the world. For example, European officials have been greatly concerned about counterfeit drugs and how sales may support high level criminal activities and terrorism. Naeem Ahmed, Head of Medicines Intelligence of the U.K. Medicines and Healthcare Products Regulatory Agency, has stated that "[i]f people buy these drugs, they should be aware of the risk they are taking as well as being aware they

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[85] Liang, *supra* note 55, at 872.

[86] *See* KATHERINE EBAN, DANGEROUS DOSES: A TRUE STORY OF COPS, COUNTERFEITS, AND THE CONTAMINATION OF AMERICA'S DRUG SUPPLY 419 (2005).

[87] *See* Liang, *supra* note 79, at 37.

[88] *See* Michael S. Schmidt, *U.S. Arrests 124 in Raids on Global Steroid Ring*, N.Y. TIMES, Sept. 24, 2007, *available at* http://www.nytimes.com/2007/09/24/sports/24cnd-steroid.html?ref=sports (last visited Oct. 31, 2007).

[89] *See* Liang, *supra* note 79, at 38. Note that Congress, including the Senior Counsel for the House Energy and Commerce Subcommittee on Oversight and Investigations, the Counsel to the Associate Commissioner for Regulatory Affairs of the F.D.A., Interpol, and private industry have all been concerned with and investigating links between counterfeit drug production and sales with terrorism. *See id.* at 37.

[90] For example, the Irish Republican Army sold fake veterinary drugs to purchase weapons. *See id*. at 38. Note that "[c]ontributing to this growth has been the increasing size and sophistication of drug counterfeiting rings and the widening involvement of organized crime groups, including the 'Russian mafia,' Chinese triads, Colombian drug cartels, Mexican gangs, and even terrorist groups such as Hezbollah, IRA and ETA." WYATT YANKUS, COUNTERFEIT DRUGS: COMING TO A PHARMACY NEAR YOU 2 (2006), *available at* http://www.acsh.org/publications/pubid.1384/pub_detail.asp (last visited Nov.14, 2007).

may be supporting organi[z]ed crime or terrorism."[91] Further, Madame Maud de Boer-Buquicchio, Deputy Secretary of the Council of Europe, has echoed this theme. She notes that:

> [S]everal indicators suggest that organi[z]ed crime has found a currently lucrative and nearly safe business of counterfeiting medicines to generate resources for other criminal activities. Organi[z]ed 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.[92]

These issues have been a subject of concern for U.K. Members of Parliament. For example, Mr. Charles Walker, MP, indicated that "[t]he profits from pharmaceutical counterfeiting are huge and the risks lower than those involved in trafficking [illicit] narcotics. Counterfeiting is linked to all forms of organi[z]ed crime such as money laundering, drug trafficking, terrorism, and other illegal activities."[93]

Indeed, for Viagra® alone, Pfizer has reported that from 1999, when the first counterfeit Viagra® tablet was found in the U.K., to June 30, 2006, it has discovered fakes being sold in more than sixty-five countries.[94] Further, the Pharmaceutical Security Institute, a non-profit association that includes twenty-two brand name pharmaceutical corporation security directors, has compiled information indicating that greater than 100 countries around the world were linked to pharmaceutical crime and counterfeiting; that the two top countries exporting counterfeits were China and India; and that hundreds of

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[91] Celia Hall, *Internet Fuels Boom in Counterfeit Drugs*, THE TELEGRAPH (U.K.), Aug. 16, 2005, *available at* http://www.telegraph.co.uk/news/main.jhtml?xml=/news/2005/08/16/ndrugs16.xml (last visited Aug. 28, 2007).

[92] *See* Maud de Boer-Buquicchio, Deputy Sec'y Gen., Council of Eur., Opening Speech for the Seminar "Counteract the Counterfeiters!": Limiting the Risks of Counterfeit Medicines to Public Health in Europe by Adequate Measures and Mechanisms (Sept. 21, 2005), *available at* http://www.coe.int/T/E/Com/press/News/2005/20050921_disc_sga.asp (last visited July 3, 2007); *see also* Arthur Rogers, *Council of Europe Weighs Accord on Curbing Counterfeit Drugs*, 71 BNA PAT., TRADEMARK & COPYRIGHT J. 700, 700 (2006) (noting E.U. and Council of Europe expression of concern regarding the Internet and counterfeit drug sales).

[93] 441 PARL. DEB., H.C. (6th ser.) (2006) 1639, *available at* http://www.publications.parliament.uk/pa/cm2000506/cmhansrd/cm060126/debtext/60126-40.htm (last visited July 12, 2007).

[94] *See* Theriault, *supra* note 47, at 47.

different products for virtually all organ systems and diseases are involved.[95] These trends indicate the vast scope of the public health issue and the involved criminal element represented by counterfeit drugs.

III. SOURCES OF THE PROBLEM

A. High Prices for Real Drugs

The global trade in counterfeit drugs is astounding. The World Health Organization currently estimates that annual global sales of counterfeit drugs total roughly $40 billion annually, or $110 million each day.[96] Further, by 2010, it is estimated that counterfeit drug sales will reach $75 billion annually, which amounts to more than $205 million daily.[97] The counterfeit drug market is attractive because of

[95] *See* Thomas T. Kubic & Sebastian J. Mollo, *Pharmaceutical Counterfeiting Trends: Understanding the Extent of Criminal Activity*, 9(4) J. BIOLAW & BUS. 51, 53-54 (2006). Unfortunately, these operations are expanding. *See, e.g.*, Jonathan Calvert et al., *Factory for Fake Prescription Drugs*, SUNDAY TIMES ONLINE (U.K.), Sept. 23, 2007, http://www.timesonline.co.uk/tol/news/uk/health/article2511583.ece (last visited Sept. 23, 2007) (reporting undercover *London Times* investigation setting up a fake wholesaler business and obtaining counterfeit materials in China, including lifesaving blood-thinning drugs, prostate cancer drugs, and a schizophrenia drug, as well as revealing extensive operations in counterfeit drugs and limited regulatory oversight). Indeed, a study of wholesaler exchange sites selling bulk quantity drugs that are of questionable legitimacy found that 31% were listed in China, followed by 26% in the United States and 19% India. Press Release, MarkMonitor Brandjacking Index Exposes Online Scams That Threaten Top Pharmaceutical Brands and Hurt Consumers, MarkMonitor (Aug. 20, 2007), http://www.markmonitor.com/news/press-070820.html (last visited Oct. 26, 2007) [hereinafter Press Release, MarkMonitor]. This analysis showed that when assessing only six brand drugs and twenty-one websites, 75 million pills were available with a conservative wholesale value of $150 million. *Id.* Another analysis found that more than 1,300 Chinese chemical companies were openly advertising pharmaceutical ingredients on business-to-business Internet sites, with most, if not all, not certified by China's drug authorities. *See* Walt Bogdanich**,** *Chinese Chemicals Flow Unchecked to Market*, N.Y. TIMES, Oct. 31, 2007, at A1. In a refreshing show of honesty, one Chinese chemical manufacturer indicated that "[w]e don't have the resources and means to produce medicine. The bar for producing chemicals[, however,] is pretty low." *Id.* (quoting Gu Jinfeng, salesman for Changzhou Watson Fine Chemical). Yet the manufacturer advertises that it makes pharmaceutical ingredients, and that he "would export them only to countries with lower standards than China, or if '*we can earn really good profits*.'" *Id.* (emphasis added).

[96] *See, e.g.*, Frances Williams, *Taskforce Set Up to Tackle Counterfeit Drugs*, FINANCIAL TIMES (London), Feb. 15, 2006, *available at* http://news.ft.com/cms/s/1424e002-9e51-11da-b641-0000779e2340.html (last visited July 3, 2007).

[97] *See* William Burns, *W.H.O. Launches Task Force to Fight Counterfeit Drugs*, 84 BULL. WORLD HEALTH ORG. 689, 689 (2006), *available at* http://www.who.int/bulletin/volumes/84/9/news.pdf.

the high prices and profits associated with the legitimate products they are copying.

The cost of pharmaceutical innovation is high. Development of a new drug is estimated to cost between $800 million[98] and $1.2 billion dollars.[99] Consequently, a concomitant high price is required to sustain a return on this investment. Further, the pharmaceutical industry notes that in addition to the significant resources necessary to research and develop effective drugs, very few chemical compounds ever reach the clinical trial stage, and only a small percentage of those drugs are approved by the F.D.A.[100] Hence, pharmaceuticals must account for these factors in pricing drugs to continue innovation and development of new medicines.[101]

This pricing is implemented through intellectual property protections, specifically patent rights of exclusion, which allow for monopoly pricing for pharmaceutical innovation.[102] This regime allows higher-than-competitive prices for the duration of the patent.[103] Because few drugs are actually approved by the F.D.A. and sold, and because roughly 20% of those drugs generate 70% of returns, the successful 20% must be priced higher to recoup the cost of continued

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[98] *See* John A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH & ECON. 151, 166 (2003).

[99] For example, the cost to develop a biologic drug is roughly $1.2 billion, and requires an average of 97.7 months for approval. *See* Tufts Center for the Study of Drug Development, *Average Cost to Develop a New Biotechnology Product Is $1.2 Billion*, http://csdd.tufts.edu/NewsEvents/NewsArticle.asp? newsid=69 (last visited Aug. 27, 2007).

[100] According to industry estimates, the F.D.A. approves only one drug of 10,000 compounds developed by pharmaceutical companies. *See* PHARM. RES. & MFRS. OF AM., INNOVATION (2007), http://www.phrma.org/innovation/ (last visited Oct. 29, 2007).

[101] *See* PHARM. RES. & MFRS. OF AM., WHAT GOES INTO THE COST OF PRESCRIPTION DRUGS? 3 (2005), http://www.phrma.org/files/Cost_of_Prescription_Drugs.pdf.

[102] Ian Maitland, *Priceless Goods: How Should Life-Saving Drugs Be Priced?*, 12 BUS. ETHICS Q. 451, 462 (2002). It has been noted that "[p]atents are generally considered necessary to encourage R&D, particularly in an R&D-intensive industry such as pharmaceuticals." Patricia M. Danzon & Adrian Towse, *Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents* 1 (AEI-Brookings Joint Ctr. for Regulatory Studies, Working Paper 03-7, 2003). Further, "[t]he economic purpose of patents is therefore to bar entry of copy products for the term of the patent, to provide the innovator firm with an opportunity to price above marginal cost and thereby recoup R&D expense, in order to preserve incentives for future R&D." *Id.* § 2, at 2.

[103] *See* Maitland, *supra* note 102, at 462. Note, however, that branded drugs in the same therapeutic category, such as progressively newer cholesterol drugs called statins, may have to compete against each other even during the patent period. *See, e.g.*, Panos Kanavos et al., *Product Differentiation, Competition and Regulation of New Drugs: The Case of Statins in Four European Countries*, 28 MANAGERIAL & DECISION ECON. 455, 463-64 (2007).

research and development across product lines and development efforts.[104]

Hence, the price of brand name drugs is high, particularly in the U.S.[105] It has been argued that the U.S. "subsidize[s] the world" and "fund[s] the bulk of the research for the rest of the world so everyone else can mooch."[106] Arguably, high prices result in quicker access to drugs for U.S. consumers—at least to those who can afford the price of brand name drugs—than for consumers in European countries instituting price controls.[107] This leads to the argument that any price controls "will likely only hurt patients by discouraging needed investment in new research."[108]

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[104] *See* PHARM. RES. & MFRS. OF AM., *supra* note 101, at 15.

[105] *See, e.g.*, Richard G. Frank, *Prescription-Drug Prices*, 351 NEW ENG. J. MED. 1375 (2004). This is not a new phenomenon. *See* Gina Kolata, *Why Drugs Cost More in U.S.: Other Governments Negotiate Prices*, N.Y. TIMES, May 24, 1991, at D1 (reporting that Americans, at the time, paid 54% more than Europeans for twenty-five commonly prescribed drugs).

[106] *See* Maitland, *supra* note 102, at 466 (quoting economists Richard Zeckhauer and Uwe Reinhardt).

[107] *See id.*

[108] *See id.* This rationale has been equated to rent controls leading to shortages of rental units, and price controls on gasoline leading to long lines of cars at the pumps. *See id.* at 458. It should also be noted that this perception of high prices may not necessarily be as dramatic as some believe. For example, market forces in the U.S. determine consumer prices so that there is a wide variation in rates and discounts associated with drugs sold here. *See* PHARM. RES. & MFRS. OF AM., *supra* note 101, at 10. Hence, in some cases, "for the nearly 75% percent [sic] of Americans with health insurance coverage and for whom institutional purchasers negotiate often deeply discounted medicine prices," prices may be less that what they would pay for the same drug in other countries such as Canada. *Id.* The Canadian Competition Bureau has noted in a generic drug pricing study that Canadian prices for generic drugs are higher than ten of eleven comparative nations. *See* CANADA COMPETITION BUREAU, CANADIAN DRUG SECTOR STUDY 21 (2007), *available at* http://www.competition bureau.gc.ca/PDFs/Competition%20Bureau%20Generic%20Drug%20Sector%20Study.pdf. The Office of Inspector General has also noted that if mandated price discounts, as applied to brand-name firms, were also applied to generic firms, the Medicaid program would have received a total of $966 million in additional rebates for the top 200 generic drugs from 1991 through 2004. *See* Memorandum to Kerry Weems, Office of Inspector General, Review of Generic Drug Price Increases, A-06-07-00042 (Oct. 24, 2007), *available at* http://www.oig.hhs.gov/oas/reports/region6/60700042.pdf (also noting that generic drug price increases exceeded the specified statutory inflation factor applicable to brand-name drugs for 35% of the quarterly average manufacturer prices reviewed).

B. High Prices: The Counterfeit Seller-Buyer Interface

Of course, those without insurance or the ability to pay out-of-pocket for drugs are left out of the market.[109] Indeed, those without insurance do not benefit from group purchasing arrangements in the private insurer markets or from public beneficiaries such as the government and the military, and therefore are left to pay full price for their drugs.[110] One estimate indicates that the uninsured in the U.S. pay not only the highest prices for drugs of all patients in the U.S., but indeed, pay the highest prices in the world.[111]

Hence, the reality[112] is that prices for medicines in the U.S. are high, and this fact drives price-sensitive patients, such as minorities, the uninsured, and seniors, to seek cheaper drugs from questionable

[109] *See* Danzon & Towse, *supra* note 102, at § 2, at 3 ("U.S. and other evidence indicates that powerful third party payers obtain lower prices than out-of-pocket purchasers") (footnote omitted).

[110] *See, e.g.*, BLAIR HORNER & TRACY SHELTON, N.Y. PUB. INTEREST RESEARCH GROUP, PAYING THE PRICE: THE HIGH COST OF PRESCRIPTION DRUGS FOR UNINSURED CONSUMERS 10 (2004), *available at* http://www.nypirg.org/consumer/drugreport/paying_the_price.pdf; *see also* U.S. PUB. INTEREST RESEARCH GROUP, PAYING THE PRICE: THE HIGH COST OF PRESCRIPTION DRUGS FOR UNINSURED CONSUMERS (2006) (summarizing figures for other parts of the U.S.).

[111] *See* HORNER & SHELTON, *supra* note 110, at 4. Unfortunately, these patients are much more likely to get their care at an expensive site of care, such as the emergency department, straining the health care dollar even further. *See, e.g., Emergency Room Visits Reach Record High*, MSNBC.COM, May 26, 2005, http://www.msnbc.msn.com/id/7995137/ (last visited Nov. 3, 2007) (noting "[e]mergency departments are a safety net and often the place of first resort for health care for America's poor and uninsured").

[112] It should be noted that there is significant debate as to how much it actually costs to develop a new drug. Advocates point out that, although it is very expensive to develop drugs, it is not nearly as expensive as pharmaceutical companies claim. For example, government funding accounts for a significant amount of the resources necessary for research leading to new drugs, and, in fact, tax deductions for research and development may reduce the cost of drug development to less than a third of industry estimates. *See* PUBLIC CITIZEN, WOULD LOWER PRESCRIPTION DRUG PRICES CURB COMPANY RESEARCH & DEVELOPMENT?, http://www.citizen.org/congress/reform/drug_industry/r_d/articles.cfm?ID=7909 (last visited Oct. 29, 2007) (claiming $800 million estimate is flawed and actual estimates for drug development, taking into account cost of capital adjustments and tax, reduced figure to $240 million). In addition, costs of marketing actually represent a greater source of cost for drugs than research and development, and, therefore, are a more important factor in high prices. *Id.* (reporting that spending on advertising increased at a much faster rate (32%) in 2000 than spending on research and development (13%)).

sources.[113] It is at this social interface where counterfeit sellers interact with vulnerable buyers.

This interface includes the Internet, foreign countries such as Mexico, open markets, and other non-traditional sources of drugs, which are accessed by patients who cannot afford standard pricing for medicines. Hence, small markets have sprouted and have been found to sell tainted and counterfeit drugs, particularly in minority communities.[114] Seniors go over the border to Mexico on bus trips to buy prescription drugs.[115] The uninsured turn to the Internet to obtain access to their medications at a cheaper price.[116] For all of these individuals, the choice is between taking the chance that they might not be getting the medicine they think they purchased, but at least having some chance for cure, or, without taking such a risk, having no chance at all of obtaining the desired drug and forgoing any chance for effective treatment.

The problem is compounded because these buyers who enter the nontraditional market for drugs and risk receiving counterfeits have little knowledge of the scope or presence of that risk.[117] Despite

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[113] *See, e.g.*, Lisa Reyes, *Prescription Drugs Sold Illegally*, NEWS 14 CAROLINA, July 20, 2005, *available at* http://www.talkaboutdrugsnetwork.com/group/alt.drugs.viagra/messages/1650.html (last visited Aug. 2, 2007).

[114] *See id.*

[115] *See Senior Day-Trippers Seek Cheap Prescriptions*, KVOA NEWS 4, Apr. 29, 2005, *available at* http://www.kvoa.com/Global/story.asp?S=3278532 (last visited Aug. 4, 2007).

[116] *See* Chrissy & Company, *Prescription Drugs Online? Know the Risks!*, AC: ASSOCIATED CONTENT, Feb. 1, 2007, http://www.associatedcontent.com/article/127401/prescription_drugs_online_know _the.html (last visited Oct. 31, 2007). In addition, the F.D.A. indicates that some may be accessing the Internet because they are avoiding the use of a physician or do not have access to one. *See Consumers Continue to Buy Risky Drugs Online, F.D.A. Says*, 5(4) BNA PHARMACEUTICAL L. & INDUSTRY 1172 (2007). In its review of online buying, the F.D.A. investigation surveyed international mail facilities and courier facilities across the country from September 2006 to August 2007. It found that 88% of the 2,069 packages examined were prescription drugs available in the U.S.; 53% had generic versions in the U.S.; and 47% of the sampled products could be purchased for $4 at several U.S. national chain pharmacies. *See id.* The F.D.A. also noted the cheaper prices of generics compared with other countries. *See id.* Importantly, "several drugs found in the investigation require special monitoring by physicians or other health care professionals for potential adverse events and to ensure their effectiveness. These include antibiotics, antidepressants, the blood thinner warfarin, and levothyroxine (a thyroid replacement hormone)." *Id.* This dynamic may be associated with limited access to health insurance, which precludes easy access to physicians, prescriptions, and achieving health care goals. *See infra* note 321 and accompanying text (noting access to health insurance provides access to health through high-quality health care services).

[117] The F.D.A. notes that a critical aspect of its mission is to educate and heighten awareness of consumers about the risk of counterfeits. *See* F.D.A., COMBATING

at least some information on the dangers of counterfeits, consumers purchasing from suspect sources have apparently not gotten the message or have ignored it in the face of a choice between no drug or some chance of one.[118] A recent survey of U.S. patients found that 15% of respondents had purchased drugs online.[119] Yet the vast majority (93%) of these respondents who had purchased prescription drugs never suspected that they might be counterfeit.[120] Importantly, even though greater than half (53%) of these online drug purchasers said there is no way to tell if a drug is real or counterfeit, they still purchased the drug.[121] Also, in a poignant indication of how much patients are willing to risk—or an illustration of the naïvité of these purchasers—about one-fourth (27%) said that if the online pharmacy guaranteed the medication was genuine, that was good enough for them.[122] Importantly, seniors were found to be the largest group to purchase online.[123]

However, as noted by Howard Zucker, Assistant Director-General for Health Technology at the World Health Organization, the presence of counterfeits is real. He indicates that "[w]e need to help people become more aware of the growing market in counterfeit medicines and the public health risks associated with this illegal practice."[124] Yet, for the U.S., if safety initiatives continue to ignore price, alternative markets will continue to thrive where price-sensitive patients meet with questionable sellers preying upon patient hopes for treatment at a price they can afford.

COUNTERFEIT DRUGS: A REPORT OF THE FOOD AND DRUG ADMINISTRATION ANNUAL UPDATE (2005), *available at* http://www.fda.gov/oc/initiatives/counterfeit/update2005.html (last visited Nov. 2, 2007).

[118] *See* NATIONAL CONSUMERS LEAGUE, COUNTERFEIT DRUG SURVEY (2004), http://www.nclnet.org/pressroom/fakedrugsreport.htm (last visited Nov. 2, 2007).

[119] *See id.*

[120] *See id.*

[121] *See id.*

[122] *See id.*

[123] *See id.* Even in parts of the world where counterfeits are relatively well-known, such as the E.U., there is very limited knowledge as to the risks of counterfeits. *See, e.g.*, Katrina Megget, *Survey Asks: What to Do About Counterfeit Drugs?*, IN-PHARMA TECHNOLOGIST.COM, Oct. 30, 2007, http://www.in-pharmatechnologist.com/news/ng.asp?n=80987-together-health-who-counterfeit-drugs-legal-intervention-impact (last visited Nov. 2, 2007) (reporting an E.U. study that found only 18% of patients were concerned about counterfeit drugs, reflecting "a worrying lack of knowledge among patients and patient organi[z]ations into the scale of the counterfeit medicines problems across Europe.").

[124] *See* Burns, *supra* note 97.

C. Low Cost of Fakes

The combination of high brand name prices and a ready demand makes the U.S. an attractive market to counterfeiters who can produce fakes at a lower cost than can legitimate pharmaceutical manufacturers. Of course, the costs of manufacturing counterfeit drugs are not merely somewhat lower—they are much, much lower. This results in higher marginal gains compared to other illicit activities available to the unsavory looking to make large amounts of quick cash.

First, consider the other profitable drug market: illicit drugs such as heroin or cocaine. Although profit margins for engaging in this market can be quite high, making and distributing these drugs is expensive and technologically complex. Moreover, collection of the proceeds is fraught with troubles, and the endeavor is risky, with the ever-present threat of criminal penalties and active law enforcement attention.[125] Furthermore, these products must have physiological effects to garner the appropriate market distributors and purchasers, i.e., they must actually work.[126]

In contrast, consider counterfeiting licit drugs. Such a business avoids virtually all of these pesky concerns. Counterfeiting licit drugs is cheap: only appearances require attention, not physiologic function.[127] Manufacturing is cheap: unskilled labor can make the simple fake product without concerns regarding any complex manufacturing conditions, scientific know-how, or synthetic processes, unlike the production of cocaine or heroin.[128] And, most importantly, the costs of getting caught are cheap—there are very few enforcement efforts, and penalties are extremely light when compared to those associated with illicit drug production.[129]

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[125] *See* Liang, *supra* note 74, at 486.
[126] *See id.* at 486-87.
[127] *See id.* at 487.
[128] *See id*.
[129] *See id.* at 487 n.15. Indeed, under U.S. pressure, Latin American countries have increased penalties for *illicit* drug production, which may result in ten to fifteen years in a Latin American prison. *See* Liang, *supra* note 8, at 286; *see also* Sarah Boseley, *Made for 25p, Sold for £15: The Fake Viagra that Netted Pill Gang Millions*, GUARDIAN UNLIMITED (U.K.), Sept. 18, 2007, *available at* http://www.guardian.co.uk/crime/article/0,,2171476,00.html (last visited Sept. 18, 2007) (reporting largest counterfeit drug bust in U.K. history was fortuitous but only resulted in sentence of 4.5 years for lead player). Penalties for manufacture and sale of counterfeit *licit* drugs are light—only six months in jail, with bail procured in just a few days. *See* Liang, *supra* note 8, at 286. This fact has resulted in an increase of counterfeit licit drug production in this region for export as well as within domestic borders. *See id.* Note, however, that limited penalties are not simply the province of Latin American countries. The U.S. is similar; trademark counterfeiting will result

So, ultimately, there are very, very low financial and personal risks associated with manufacturing fake drugs since pecuniary and social costs of production are limited. Hence, it has been reported that fakes can be made for a total cost of as little as $0.01 per tablet—much less than illicit drugs–while being sold for $0.30,[130] resulting in a much higher profit margin. Moreover, the penalty may simply be a fine, perhaps akin to a regulatory cost of doing business.[131]

It is therefore not surprising that the high price of legitimate medicines and the low cost of producing fake ones make entry into the counterfeit drug market highly appealing to the enterprising but unscrupulous businessperson. In combination with easy distribution, such as through the Internet, limited regulatory detection, and virtually no accountability, the potential profits are considerable—as are the public health risks to the polity.[132]

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in up to ten years in jail, but counterfeiting a licit drug only up to three years. *See id.* at 287. Often, no jail time is involved. *See, e.g.*, *Londonderry Drug Firm Admits to Selling Fake Cialis*, BOSTON.COM, Sept. 6, 2007, http://www.boston.com/news/local/new_hampshire/articles/2007/09/06/londonderry_drug_firm_admits_to_selling_fake_cialis (last visited Sept. 26, 2007) (reporting seller of fake Cialis® imported from India only faces fines for activities); Associated Press, *L.A. Man Sentenced in Fake Viagra Case*, May 17, 2005, *available at* http://dailynews.muzi.com/news/ll / english/1363157.shtml?cc=25506 (last visited Sept. 1, 2007) (man caught smuggling and manufacturing counterfeit Viagra given six months home detention and 2,500 hours community service as penalty). Canada is similar. *See* STANDING COMMITTEE ON PUBLIC SAFETY AND NATIONAL SECURITY, HOUSE OF COMMONS, CANADA, 10TH REPORT 8-9 (2007), *available at* http://cmte.parl.gc.ca/Content/HOC/ committee/391/secu/reports/rp2985081/securp10/securp10-e.pdf (reporting that penalties for counterfeiting are a CDN$2000 and six months to two years imprisonment). European penalties also reflect this peculiarity in punishing counterfeit licit drug dealers. *See* Liang, *supra* note 74, at 495-96; *"Viagra Peddler" Goes on Trial,* THE LOCAL (Sweden), Aug. 30, 2007, *available at* http://www.thelocal.se/8333/ 20070830 (last visited Sept. 26, 2007) (reporting sale of fake drugs in Sweden carries penalties of only up to two years in prison); Abbott, *supra* note 68 ("Under the Medicines Act you are likely to receive just two to three years in jail for dealing in counterfeit medicines.").

[130] Kerry Capell & Suzanne Timmons, *What's in That Pill? In Latin America, Fake Drugs Are as Lucrative as Cocaine*, BUS. WEEK, June 18, 2001, at 60, *available at* http://www.businessweek.com/ magazine/content/01_25/b3737153.htm (last visited Aug. 3, 2007).

[131] *See supra* note 129 (describing limited penalties for counterfeiting drugs).

[132] Examples of the ability to avoid accountability for Internet-based sales of fake drugs are numerous. They include:

> 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. F.D.A. tracked it down to look at it; they found out that the Internet service provider was in China. They

D. The Gray Market and Parallel Trade

Beyond the price and cost allure of counterfeit drug production, the system of distribution of medicines has significant vulnerabilities that allow fakes to enter. These vulnerabilities exist both in the U.S. as well as internationally. The greatest challenge is the potential for drugs to move from wholesaler to wholesaler without accountability. In the U.S., this occurs in the secondary, or "gray" market, and internationally, such as in the E.U., through a process known as parallel trade.

1. The Gray Market

Generally, 90% of drugs in the U.S. move from the manufacturer to large wholesalers, who then distribute directly to primary sellers such as pharmacies, hospitals, and nursing homes.[133] Three large bulk wholesalers distribute this 90% share: Amerisource Bergen, Cardinal Health, and McKesson Corporation (the "Big Three").[134]

However, the remaining 10% of drugs in the U.S. pass through the secondary or gray market, i.e., through an array and complex network of smaller and larger wholesalers and providers who trade with each other, representing thousands of interactions and hands through which shipments of drugs may pass. Although there are legitimate players in this secondary market, it is here that counterfeits can enter into the supply chain.[135]

> found that the [website] 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.

Liang, *supra* note 8, at 312 (quoting Michael O. Leavitt, Sec'y of Health & Hum. Servs.). "For example, a web address may be licensed in Russia; the server in China; the company payee for the credit card charge in the United Kingdom; the processing of payment in Australia; and the product mailed from Chicago, *using a return address of an unsuspecting customer of the website*." Liang, *supra* note 55, at 862-63 (emphasis added). "Though [the Internet seller was] based in Costa Rica, [the seller] spread its operations out across the globe. Computer servers were located in Cyprus, credit card payments were processed through a company in Israel and revenues were placed in bank accounts in Cyprus." *See* Moran, *supra* note 43 (quoting Lorraine Concha, Assistant Special Agent in Charge of the Immigration & Customs Enforcement Agency).

[133] Liang, *supra* note 8, at 287.

[134] *Id.*

[135] *Id.*; *see also* Donald deKeiffer, *Trojan Drugs: Counterfeit and Mislabeled Pharmaceuticals in the Legitimate Market*, 32 AM. J.L. & MED. 325 (2006)

How can this work? Fundamentally, in these circumstances, trade is indirect, with repeated variations. For example:

- the Big Three may buy back drugs from smaller secondary wholesalers to cover shortages;
- pharmacies and others may sell stock amongst themselves and to and through secondary wholesalers for cash flow purposes;
- excess supplies with impending expirations may be sold between and among large and small wholesalers, pharmacies, hospitals, and other providers;
- bulk drugs may be sold to repackagers and other parties to create consumer-level products;
- arbitrage may occur amongst sellers;
- and/or a repeated cycle of any and/or all of these and other indirect transfers of drugs.[136]

In this way, drugs may pass back and forth through many wholesalers, retailers, and repackagers before reaching the patient.[137] Because of the complexity of and number of transfers, there are multiple points for counterfeits to be introduced into the supply chain.

Regulation of gray market sales is highly fractionated and weak. Distribution, repackaging, dispensing, and pharmaceutical product returns by purchasers are state law concerns.[138] Unfortunately, there are few requirements and inadequate staffing to perform appropriate inspections and enforcement of rules by the states.[139] In general, states do not require wholesalers to follow or maintain transfer records,[140] and there is little coordination between

(discussing how counterfeit drugs use the gray market to enter the distribution chain).

[136] Liang, *supra* note 8, at 288.

[137] *Id.*

[138] *Id.*

[139] *Id.*

[140] *See infra* notes 188-206 and accompanying text (discussing pedigree system limitations); *infra* notes 207-209 and accompanying text (discussing fractionated state efforts to track drug pedigree).

state regulatory authorities.[141] Complicating matters, prescription drug approval and manufacturing regulatory authority rests with the federal government, again with limited coordination with state agencies.[142] These dual regulatory systems with inadequate resources result in tremendous gaps in the safety regulatory structure. Such limitations create concomitant accountability gaps in the gray market, allowing parties who wish to sell fake drugs to surreptitiously pass their products into the distribution chain and into the patient who purchases and consumes the tainted medication.[143]

2. Parallel Trade

The domestic vulnerability issues in the U.S. regarding drug safety in the gray market are mirrored internationally. This is illustrated by the E.U. system of parallel trade.

Parallel trade in the E.U. is economically and regulatorily encouraged. As noted by the World Health Organization and others, on one level, differential pricing amongst European countries allows arbitrage to occur, and provides economic incentives for potential sellers in one country with lower costs to move their goods for sale in another with higher prices. Unfortunately, this provides a window for poor quality and fake products to enter the marketplace.[144]

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[141] *See infra* note 207 (noting conflicting pedigree requirements across states).

[142] Liang, *supra* note 8, at 288. Indeed, several federal governmental agencies have authority over prescription drugs. These include the F.D.A., the Drug Enforcement Administration, Customs and Border Protection, Immigration and Customs Enforcement, the U.S. Postal Service, and the Office of National Drug Control Policy. *See* GOV'T ACCOUNTABILITY OFFICE, PRESCRIPTION DRUGS: ENHANCED EFFORTS AND BETTER AGENCY COORDINATION NEEDED TO ADDRESS ILLEGAL IMPORTATION, GAO-06-175T, at 2-3 (2005).

[143] Liang, *supra* note 8, at 288.

[144] *See* WORLD HEALTH ORG., 18 WHO DRUG INFORMATION (2004), http://www.who.int/druginformation/vol18num2_2004/DI18-2.pdf (last visited Jan. 31, 2008). As noted by William K. Hubbard, former Associate Commissioner of the F.D.A.:

> [U]nlike the relatively closed U.S. drug market, in most countries these products are subject to normal arbitrage, which means that drugs move about [as] much as do electronics, apparel, auto parts and thousands of other goods. This has meant that drugs are often purchased from suppliers who have little or no oversight by regulatory bodies; that key elements of safe drug production are ignored—such as quality testing, expiration dating, and labeling controls; and that producers of substandard and counterfeit drugs have a relatively easy access to the marketplace.

As mentioned earlier, formal E.U. policy encourages parallel trade. Under Articles 28 and 81 of the European Commission Treaty for the Free Movement of Goods and Services within the Internal Market of the E.U. Countries,[145] parallel trade in pharmaceuticals specifically is permitted. Under these provisions of free movement of goods and services, no individual country may place any barrier—legal, legislative, or otherwise—that prevents trade in pharmaceuticals and other products between E.U. members.[146] Indeed, the emphasis upon free trade between E.U. countries for pharmaceuticals is strong. For example, an owner of a trademark cannot use these intellectual property-related rights to prevent any repackaging of a pharmaceutical product if the repackaging does not adversely affect the original condition of the product.[147] In this fashion, the regulatory climate is similar to the U.S. gray market—drugs can be moved through many places, touched by many persons, and repackaged multiple times by the scrupulous and unscrupulous before being ingested by or injected into the patient.[148]

Parallel trade has become a significant source of counterfeit drugs. In the summer of 2007, it accounted for at least three large scale government investigations and intercessions.[149] Again, as in the United States, changing hands, using wholesalers, and repackaging multiple times creates easy[150] opportunities for counterfeiters to

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Statement of William K. Hubbard, *supra* note 25, at 4. Because of these price differentials, "hugely divergent prices exist … which in turn allows counterfeit products to be introduced." *See* Global Forum on Pharmaceutical Anti-counterfeiting, *Calls for Increased Corporate Responsibility and a Framework Convention*, EMEDIA WIRE, Mar. 21, 2005, http://www.emediawire.com/releases/2005/emw219649.htm (last visited Jan. 31, 2008) (describing the Second Global Forum on Pharmaceutical Counterfeiting, in Paris, France, and policy statements that emanated from it).

[145] *See Commission Communication on Parallel Imports of Proprietary Medicinal Products for which Marketing Authorizations have Already Been Granted*, at 6, COM (2003) 839 final (Dec. 30, 2003), *available at* http://eur-lex.europa.eu/LexUriServ/site/en/com/2003/com2003_0839en01.pdf; Nigel Gregson et al., *Pricing Medicines: Theory and Practice, Challenges and Opportunities*, 4 NATURE REVS.: DRUG DISCOVERY 121, 128 (2005).

[146] *See* Liang, *supra* note 55, at 852.

[147] *Id*.

[148] *Id*.

[149] *See* Abbott, *supra* note 68.

[150] A fraudulent parallel trade business is quite simple to set up, even in "developed" countries such as the U.K. For example, a fake business was created with empty boxes and a single refrigerator in the U.K., which then obtained a parallel trade license, and then contracted with a convicted, known pharmaceutical counterfeiter for supplies. This business then obtained agreements to sell drugs to pharmacies and hospitals. *See Tonight with Trevor McDonald: Is Your Medicine Fake?* (ITV television broadcast Jan. 9, 2006); *see also* Liang, *supra* note 55, at 856-57 (quoting

introduce their products into the market.[151] These circumstances have resulted in calls for scrutiny of the current regulatory safety structure.[152]

MPs Concerned Over Parallel Import Threat to Patient Safety, CHEMIST & DRUGGIST (U.K.), Dec. 17, 2005 (reporting comments by Dr. Brian Iddon, MP, who called for investigations of parallel trade after Parliamentary debate highlighted safety concerns)). In addition, in a more concerning trend, Chinese manufacturers making legitimate drugs by day convert to fake drugs at night:

> A recent "sting" operation by the *Sunday Times* of London set up a phony drug wholesaler, who was able to buy large quantities of counterfeit drugs from a Chinese manufacturer, who was reported to make pharmaceutical ingredients for legal sale by day and fake drugs for illicit sale by night. The *Times* reported that counterfeiters are increasingly turning from fake handbags and currency to drugs, because the drugs are *so easy to make and sell on world markets*.

Statement of William K. Hubbard, *supra* note 25, at 4 (emphasis supplied).

[151] For example,

> The trade is not as simple as a drug being sold from a wholesaler in one country to a distributor in Britain. It could be repackaged first in another country, say France, then sold to a wholesaler there and passed on again to a third or even a fourth country where it might be repackaged yet again.

See Abbott, *supra* note 68. *See also supra* notes 146-148 and *infra* note 209 and accompanying text (describing the limits of any system relying on tracking packaging because repackaging is legal, and for safety a system must track the drug).

[152] Fake Lipitor has been found in the U.K. salted with real Lipitor. *See* Press Release: Drug Alert Class 2 Medicines Recall (Action within 48 Hours): Lipitor Tablets 20mg, Atorvastatin (as Calcium Trihydrate), PL 16051/0002, U.K. M.H.R.A., July 28, 2005, *available at* http://www.mhra.gov.uk/home/groups/is-md/documents/drugalert/con2018023.pdf; Lister, *supra* note 63, 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 E.U. showed that counterfeit medicines could get into any supply chain, even the U.K.'s, which is one of the most difficult to penetrate); *see also* Hall, *supra* note 91, 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 (U.K.), Aug. 20, 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 (U.K.), 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-sellling drug Lipitor, which had been packaged for the U.K. market."). These, and other

The realities of parallel trade have highlighted the significant drug safety issues facing Europe:

> [D]rug importation [via parallel trade] 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 U.K. 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.[153]

The gray market and parallel trade have been described as similar to safe sex: one may trust the person with whom one is in direct contact, but can one trust every one of the persons with whom that person had sex/got their drugs? Can one trust that all these other persons practiced safe sex/ensured appropriate storage, sources, and suppliers for the medications?[154]

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cases and investigations into counterfeit drugs, have resulted in European Commission attention to the matter and to study of the parallel trade system as applied to pharmaceuticals. *See* Lynne Taylor, *Parallel Trade "Considerable Risk" to Patient Safety, Says EC*, PHARMATIMES, Jan. 21, 2008, *available at* http://www.pharmatimes.com/WorldNews/article.aspx?id=12674&src=EWorldNews (last visited Jan. 21, 2008).

[153] *See* PROCO SOLUTIONS, DRUG IMPORTATION—TOP EUROPEAN SECURITY EXPERT WARNS SENATE PANEL ON RISKS (2005), http://www.procosolutions.com/html/drug_importation.html (last visited Aug. 2, 2007) (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 U.S. drugs, but contain different ingredients due to differences in naming across borders. *See* Marilyn Chase, *Buying the Wrong Medicine Overseas*, WALL ST. J., Aug. 16, 2005, at D1.

[154] *See* Liang, *supra* note 8, at 295.

E. The Internet

The Internet has fueled the supply of counterfeit drugs in the U.S. and abroad. Unfortunately, Internet sales appear to have reached billions of dollars annually and show no signs of abatement.[155] Internet sales are highly profitable and span the scope of pharmaceuticals and products. Recent cases include a Florida pharmacist who illegally distributed controlled substances through the Internet with sales of $4 *billion* annually before he was caught.[156] He was also convicted in a money laundering scheme.[157] Importantly, counterfeits are rampant within the Internet market for drugs. The World Health Organization estimates that up to 50% of licit drugs sold online are fake.[158] Over in the U.K., one of the largest fake Viagra® scams was uncovered with counterfeits from China, India, and Pakistan being sold over the Internet to American, British, Canadian, and other customers.[159] Up north in Canada, the counterfeit Internet sales scourge has extended to diabetic test strips. A Canadian distributor has been charged with distributing these counterfeit diabetic test strips to U.S. patients through the gray market.[160]

Pharmaceutical purchases through the Internet are highly risky. Websites may display "trusted" country flags, such as those of the U.S., U.K., or Canada, but have no location there; in fact, there is no

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[155] *See* Julie Appleby, *Canada's Cheap Drugs Not the Answer*, USA TODAY, Aug. 28, 2003; Statement of Norm Coleman, Senate Comm. on Governmental Affairs, June 17, 2004, http://senate.gov/~govt-aff/index.cfm?Fuseaction =Hearings. Testimony&TestimonyID=601&HearingID=182 (last visited Oct. 31, 2007) (consumer spending on drugs purchased over Internet in 2003 was greater than $3.2 billion).

[156] *See Fla. Pharmacist Guilty in Internet Scheme*, DRUG TOPICS, Sept. 24, 2007, http://www.drugtopics.com/drugtopics/article/articleDetail.jsp?id=459496 (last visited Sept. 24, 2007).

[157] *See id.*

[158] *See* Press Release, W.H.O. and Partners Accelerate Fight Against Counterfeit Medicines; Up to 50% of Medicines Sold Through Rogue Sites are Fake, World Health Org., Nov. 15, 2006, http://www.who.int/mediacentre/news/releases/2006/pr69/en/index.html (explaining that when there is no physical address associated or listed with the website, W.H.O. estimates that greater than 50% of drugs sold from these sources are fake); *see also* WORLD HEALTH ORG., COUNTERFEIT MEDICINES: FACT SHEET (2006), http://www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/index.html.

[159] *See Gang Guilty of Fake Viagra Scam*, BBC NEWS, Sept. 17, 2007, http://news.bbc.co.uk/2/hi/uk_news/6999160.stm.

[160] *See* Tom Blackwell, *Firm Suing Over Fake Diabetic Test Strips*, NAT'L POST (Canada), Sep.17, 2007, *available at* http://www.canada.com/nationalpost/news/story.html?id=2edf7f4c-2b09-4a4d-bd85-8f07235e0ca6&k=37047; *see also* Liang, *supra* note 8, at 288-89 n.73 (reporting counterfeit surgical mesh being sold and used in patient care).

assurance that drugs purchased from these sites are actually from these countries.[161] There are numerous examples of Canadian-registered companies that are actually foreign facilities in, for example, the Bahamas and Mexico, selling drugs not approved by Canada or the U.S.[162] Indeed, a study commissioned by the F.D.A. found that of

[161] *See* Liang, *supra* note 8, at 309 (explaining that the largest Canadian Internet seller has been caught selling counterfeit drugs to U.S. citizens that were not manufactured in Canada. Rx North was investigated after a whistleblower told a Canadian news program that drugs sold were not from Canada and were being shipped from the Bahamas); *see* Kathy Tomlinson, *Ex-worker Blows Whistle on Popular Web Pharmacy*, CTV NEWS, May 26, 2006, http://www.ctv.ca/servlet/ ArticleNews/story/CTVNews/ 20060510/whistleblower_internetdrugs_060525/ 20060525/ (reporting on Edward Hector, a whistleblower who outlined practice of using a Bahamas facility to dispense Rx North drugs not from Canada and other problematic business practices, including drugs shipped that were near expiration or with expiration dates concealed; upon further detailed investigation, fake drugs were found being sold through its Bahamas warehouse); *see Accessing the Safety of our Nation's Drug Supply: Hearing Before Subcomm. on Health of the H. Comm. on Energy and Commerce*, 110th Cong. 4 (2007) (testimony of John Theriault, Chief Security Officer and Vice-President, Global Security, Pfizer, Inc.), *available at* http://energycommerce. house.gov/cmte_mtgs/110-he-hrg.050907.Theriault-testimony.pdf. The nature of the scheme was global. U.K. authorities intercepted a four-pallet shipment of pharmaceuticals from the United Arab Emirates that included "products" made by eight drug companies that were counterfeit; these drugs' intended recipient was Personal Touch Pharmacy, in the Bahamas—whose computers were linked with Rx North's system. *See id.* at 4-5. On analysis, it was found that the blister packaging was virtually identical to the authentic product and used a legitimate product lot number. *See id.* at 5. Bahamian authorities raided the Personal Touch Pharmacy and found $3.7 million worth of products, spanning thirteen different manufacturers, constituting 3.025 million dosage units. *See id.* The Bahamian investigation has indicated that Personal Touch Pharmacy and their links with Rx North had annual sales of approximately $8 million. *See id.* The shipments used a sophisticated means of Free Trade Zones, such as Dubai, and ultimately appear to have originated from China, and were being sent through the U.K. to the Bahamas, and then back to the U.K. to hide their origins and to promote the perception of legitimacy of the drugs. *See* Walt Bogdanich, *A Toxic Pipeline: Counterfeit Drugs' Path Eased by Free Trade Zones*, N.Y. TIMES, Dec. 17, 2007, *available at* http://www.nytimes.com/2007/12/17/world/ middleeast/17freezone. html?ex=1198558800&en=2f54219f6ae8d265&ei=5070&emc=eta1 (last visited Dec. 17, 2007); *see also* Patsy Moy, *HK at Center of Global Drugs Scam*, THE STANDARD (Hong Kong), Feb. 11, 2008, *available at* http://www.thestandard.com. hk/ news_detail.asp?pp_cat=12&art_id =61319&sid =17539318&con_type=1 (last visited Feb. 12, 2008) (discussing Hong Kong as transshipment port for China counterfeit drugs, and its status as a "free port"); P. B. Jayakumar, *Asian Nations Unite Against Spurious Drugs*, BUS. STANDARD (Mumbai), Feb. 12, 2008, *available at* http://www.business-standard.com/common/news_article.php?leftnm=lmnu4 &subLeft =5&autono=313403&tab=r (last visited Feb. 13, 2008) (discussing industry, government customs, and Interpol program on counterfeits, and reporting that only 5% of medicines were inspected at free trade reports).

[162] *See* Marv D. Shepherd, Director, Center for Pharmacoeconomic Studies, Keynote Address at the Ninth Annual ASHP Management Conference for Leaders in Health-

11,000 purportedly "Canadian" websites, only 214 were actually registered to a Canadian entity.[163] Other websites selling pharmaceuticals that claim Canadian sourcing include those from Malaysia, Vanuatu, Eastern Europe, and elsewhere.[164] Importantly, it should be emphasized that even drugs shipped through countries such as Canada and within the E.U. are not subject to those countries' safety requirements if the products are not for domestic consumption.[165]

System Pharmacy: Drug Importation and the Vulnerability of Our Pharmaceutical Supply Chain 10 (Oct. 18-19, 2004), http://www.ashp.org/s_ashp/docs/files/2004 LeadershipSummary.pdf.

[163] *See* Ricardo Alonso-Zaldivar, *F.D.A. Casts Suspicion on Online Pharmacies*, SEATTLE TIMES, June 15, 2005, *available at* http://seattletimes.nwsource.com/html/ nationworld/2002336462_fda15.html (explaining countries to which the websites were registered included the United States, Vietnam, the Czech Republic, and Barbados).

[164] *See* Liang, *supra* note 8, at 310; *see also* Press Release, F.D.A. Operation Reveals Many Drugs Promoted as "Canadian" Products Really Originate From Other Countries, F.D.A., Dec. 16, 2005, *available at* http://www.fda.gov/bbs/topics/ NEWS/2005/NEW01277.html (describing Operation Bait and Switch, where F.D.A. officials that only 15% of drugs claimed to be of Canadian origin actually originated there).

[165] *See, e.g.*, Liang, *supra* note 8, at 297 & n.117.

The F.D.A.,[166] the U.K.'s M.H.R.A.,[167] and others[168] have repeatedly warned of the significant potential of fakes when consumers purchase from Internet sources. Yet the unregulated nature of Internet sales of drugs creates tremendous challenges for oversight,

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[166] *See, e.g.*, F.D.A., *F.D.A. Warns Consumers about Counterfeit Drugs from Multiple Internet Sellers*, May 1, 2007, http://www.fda.gov/bbs/topics/NEWS/2007/NEW01623.html; *Hearing on Internet Drug Sales Before the Comm. on Gov't Reform of the H.R.*, 108th Cong. 2-3 (2004) (statement of William K. Hubbard, Assoc. Comm'r for Policy & Planning), *available at* http://www.fda.gov/ola/2004/Internetdrugs0318.html; Charles W. Schmidt, *Phony Pharm*, MOD. DRUG DISCOVERY, Nov. 2002, at 27-28 (quoting William K. Hubbard during a Senate committee hearing on July 9, 2002), *available at* http://pubs.acs.org/subscribe/journals/mdd/v05/i11/pdf/1102rules.pdf?sessid=6006l3; *see also List of Rogue Online Pharmacies Published by PharmacyChecker.com*, HEALTHNEWSDIGEST.COM, Dec. 12, 2007, http://www.healthnewsdigest.com/news/World_40/List_of_Rogue_Online_Pharmacies_Published_by_PharmacyChecker_com.shtml (listing by private online system of online pharmacies that sell fake, tainted, or unsafe drugs, including many purported Canadian online sellers).

[167] *See, e.g.*, U.K. M.H.R.A., BUYING MEDICINES OVER THE INTERNET (2007), http://www.mhra. gov.uk/home/idcplg?IdcService=SS_GET_PAGE&useSecondary=true&ssDocName=CON019610.

[168] *See, e.g.*, Sarah Boseley, *Warning over Fake Drugs on the Internet*, GUARDIAN UNLIMITED (U.K.), Jan. 11, 2008, *available at* http://www.guardian.co.uk/science/2008/jan/11/drugs.health (last visited Jan. 11, 2008); Madeleine Brindley, *UK Online Medicine Warning*, ICWALES.COM, Jan. 10, 2008, http://icwales.icnetwork.co.uk/news/wales-news/2008/01/10/uk-online-medicine-warning-91466-20332263 (last visited Jan. 10, 2008); *Half Drugs on Internet "Fake or Unsafe,"* IRISHHEALTH.COM, Nov. 11, 2007, http://www.irishhealth.com/?level=4&id=12564 ; *Drug Website Safety Fears Raised*, BBC NEWS, Aug. 19, 2007, http://news.bbc.co.uk/2/hi/health/6951254.stm; *Illegal Online Pharmacies Cause Losses to Pharmaceutical Manufacturers*, HELSINGIN SANOMAT (Finland), Aug. 27, 2007, *available at* http://www.hs.fi/english/article/Illegal+online+pharmacies+cause+losses+to+pharmaceutical+manufacturers/1135229832549; *Online, Mail-Order Firms Fastest Growing Sources of Counterfeit Drugs*, IHEALTHBEAT, Apr. 28, 2005, http://www.ihealthbeat.org/index.cfm?Action=dspItem&itemID=110666; *D.E.A. Cracks Down on Illegal Rx Web Site*, REDORBIT NEWS, Sept. 21, 2005, http://www.redorbit.com/news/health/247747/dea_cracks_down_on_illegal_rx_web_site/index.html (discussing D.E.A. arrest of at least eighteen persons, registration suspensions of twenty physicians and twenty-two Internet pharmacies, shutdown of 4,600 websites, 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); *Counterfeit Drug Manufacturers Get Tough with PI Tracking Them*, PRIVATE INVESTIGATOR NEWS & INFO., Dec. 27, 2005, http://www.asginvestigations.com/pi-stories/index.php?m=200512 (describing a $4.3 million counterfeit drug operation that sold drugs to patients in Canada and the U.S. through the Internet); *Internet Pharmacies: Some Pose Safety Risks for Consumers, GAO-04-820, Testimony Before the Permanent Subcomm. on Investigations of the Comm. of Governmental Affairs*, 108th Cong. 18 (June 2004) (statement of Marcia Crosse, Director, Health Care–Public Health and Military Health Care Issues).

resulting in continuing sales of suspect products.[169] The scope of the problem is dramatic. According to one study, of more than 3,000 Internet drug seller sites most visited, only *four* had credentials from the National Association of Boards of Pharmacy,[170] and, in fact, 10% openly indicated that no prescription was necessary for drug purchases.[171]

Unfortunately, such limited oversight has resulted in the first unequivocally documented death from drugs purchased through an Internet seller.[172] This result occurred despite the fact that the F.D.A. had warned about fake drugs and the specific drug in question from this very website.[173]

This problem has been a persistent issue, as has been well-described by Representatives John Dingell and Bart Stupak:

> For the past fifteen 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

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[169] *See* Andy Greenberg, *Brandjacking Big Pharma*, FORBES, Aug. 20, 2007, *available at* http://www.forbes.com/technology/2007/08/20/brandjacking-drugs-pharmaceuticals-tech-cx_ag_0820brand.html (last visited Aug. 27, 2007) (describing challenges to public and private online sales); U.K. M.H.R.A., *supra* note 167 (describing jurisdiction and accountability issues for online sales of drugs); *Hearing on Internet Drug Sales*, *supra* note 166 (statement of William K. Hubbard, Assoc. Comm'r for Policy and Planning of the F.D.A.).

[170] *See* Greenberg, *supra* note 169 (reporting on MarkMonitor study of Internet drug sellers).

[171] *See* Press Release, MarkMonitor, *supra* note 95. Note that analysis of these websites also indicated that greater than 50% of them did not secure customer data, which places these persons at risk for identity theft.

[172] *See* Greenberg, *supra* note 169 (describing the case of Marcia Bergeron, a Vancouver woman who purchased drugs through the Internet that were laced with toxic metals including aluminum and arsenic).

[173] *See* Armina Ligaya, *Online Pharmacies: Counterfeit Drugs Caused Woman's Death, Coroner Concludes*, THE GLOBE & MAIL (Canada), July 6, 2007, *available at* http://www.bcpharmacy.ca/press_room/documents/Globeandmailclipping.pdf (reporting that with respect to the Bergeron case, "[w]hen U.S. Food and Drug Administration investigators examined her hard drive, it showed Ms. Bergeron bought Zolpidem—a powerful sedative available by prescription in the U.S., but not in Canada. The website she used, which purported to be Canadian but has since gone offline, was previously flagged by the F.D.A. concerning counterfeit Zolpidem.").

States. . . . In particular, these hearings have extensively examined the problem of rogue Internet pharmacies and how the drugs sold on these [websites] enter the U.S. through the U.S. international mail facilities and express consignment carriers, such as FedEx, UPS, and DHL.

. . . [T]hese hearings and repeated correspondence, we have provided extensive input into how and why current policies adopted by the key agencies responsible for combating this problem—namely, the Drug Enforcement Administration (D.E.A.), the Bureau of Customs and Border Protection (Customs), and the Food and Drug Administration (F.D.A.)—are ineffective . . . . It remains clear to us that the unabated flow of unregulated drugs entering the U.S. poses a growing threat to the [n]ation'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 was] overwhelming all efforts to adequately process or deny entry to the bulk of these drugs. While Customs and the F.D.A. were making some attempts to stop a portion of these drugs (mostly the controlled substances), after the purposeful release of hundreds of packages of counterfeit Sidenafil [the active pharmaceutical ingredient in 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 F.D.A. was no longer capable of addressing this problem.[174]

Legal challenges also attend. Beyond the fact that Internet presence is anonymous and easily moved and removed, foreign-based Internet websites are difficult for law enforcement to identify, track, monitor, and shut down.[175] Further, since drug laws vary by country, enforcement efforts against Internet sellers on foreign soil are often thwarted, and foreign governments may be reluctant to share information or develop mechanisms to cooperate with U.S. law enforcement efforts.[176]

Yet despite this recognition of the problem of using the Internet as a source of medicines, state importation programs continue to promote it.[177] Note that even these proponents of the state Internet importation systems appear to recognize the risks associated with purchasing online; states require that users agree to "hold harmless" provisions before accessing the website and purchasing drugs through these programs.[178] Arguably, these "hold harmless" provisions may not be legally enforceable, since it appears that state drug importation programs are illegal at the current time.[179] In this vein, it should also be noted that some of these states have actual knowledge of issues with Canadian online infrastructures for supplying drugs that were

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[174] *See, e.g.*, Letter from John D. Dingell, Ranking Member, Comm. on Energy & Commerce, and Bart Stupak, Ranking Member, Subcomm. on Oversight & Investigations, U.S. House of Representatives, Comm. on Energy & Commerce, to The Honorable Michael O. Leavitt, Sec'y, Dep't of Health & Human Servs. (July 20, 2005), http://energycommerce.house.gov/ Press_109/109ltr29.pdf.

[175] *See Prescription Drugs: Enhanced Efforts and Better Agency Coordination Needed to Address Illegal Importation: Hearing on Illegal Importation of Prescription Drugs Before the H. Subcomm. on Oversight and Investigations, Comm. on Energy and Commerce*, 109th Cong. 30 (2005) (statement of Richard M. Stana, Director, Homeland Security and Justice Issues of the Government Accountability Office), *available at* http://www.gao.gov/new.items/d06175t.pdf.

[176] *See id.* at 30-31.

[177] *See* Liang, *supra* note 55, at 866.

[178] *See id.* (outlining "hold harmless" provisions in the states of Washington, Minnesota, and Illinois Internet drug importation programs).

[179] *See* Liang, *supra* note 8, at 308 n.188; Mary Ellen Fleck Kleiman, *State Regulation of Canadian Pharmacies: A Prescription to Violate the Supremacy Clause*, 32 AM. J.L. & MED. 219, 242-45 (2006) (state importation programs violate Supremacy Clause); *see also* Devin Taylor, *Importing a Headache for Which There's No Medicine: Why Drug Reimporation Should and Will Fail*, 15 J.L. & POL'Y 1421, 1426-28 (2007) (reviewing history of state drug importation programs and some of their limitations).

discovered during pre-announced visits,[180] yet they continued to allow these programs to operate.

Ultimately, vulnerable patients purchase over the Internet because of the perceived lower cost and infrastructure that makes it a viable alternative. Indeed, with prices highly discounted over authentic drugs purchased through a legitimate pharmacy, many individuals turn to the Internet simply because they perceive they have no choice; it is a question of purchasing a drug that may or may not be authentic versus not being able to purchase any medication at all. However, as illustrated above, the threat of counterfeit drugs through Internet sales is great, and represents a significant vulnerability to consumers seeking to purchase these products. This situation has been aptly described as a "global disaster."[181]

F. Limited Suspicion and the "Perfect Crime"

In addition to the problems associated with high prices, low costs, the gray market, parallel trade, and the Internet, a tremendous source of concern regarding the problem of counterfeit drugs is the limited suspicion by health care providers and patients themselves.

Providers and patients simply do not suspect or consider fake, diverted, or adulterated medicines when therapeutic failure occurs. On one level, health care providers have almost no index of suspicion that fake drugs exist or may be an important component of clinical problems with care; consequently, they may not communicate any information on this topic to their patients. Often, providers attribute negative clinical outcomes to patient variation or to the patient succumbing to the disease, since these individuals may be frail, elderly, and/or very ill.[182] Hence patients have no awareness of the potential source of the clinical problem.

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[180] *See* Taylor, *supra* note 179, at 1444. Minnesota authorities noted many pharmacies used "unsupervised technicians" rather than trained pharmacists to enter medication orders and to answer prescription drug questions. Others reviewed 100 prescriptions and refilled 300 per hour, a volume too high to ensure safety. Further, products that required refrigeration were being shipped unrefrigerated. *Id.* Wisconsin officials found that 41% of the prescriptions filled by Canadian pharmacies were problematic, including not being approved by the F.D.A., not covered by the state drug importation program, and not refrigerated and sent by mail. *Id.* at 1445. New Hampshire officials "found conditions that were later termed 'significant safety issues'" for the online seller the state was using, CanadaDrugs.com. *Id*. at 1446.

[181] *See* Katrina Megget, *The "Global Disaster" of Fake Internet Pharmacies*, PACKWIRE, July 19, 2007, http://www.packwire.com/news/ng.asp?n=78355-americas-watchdog-fda-internet-pharmacies-counterfeit-drugs-legislative-measures (last visited Jan. 31, 2008).

[182] *See* Liang, *supra* note 8, at 289.

However, the problem of lack of suspicion is also due to the quality of the packaging and counterfeit product itself. The appearance of the product can be virtually identical to the actual drug.[183] In these situations, it is exceedingly challenging for providers and/or patients to detect a counterfeit product, even if warned about its potential presence.

Further, patients and providers have additional challenges in suspecting the presence of counterfeit drugs. Patient and caregiver lack of clinical knowledge simply prevents them from detecting fakes; this is particularly true in the many disease states where symptoms are not clearly impacted after taking the drug.[184] In addition, providers contribute to these difficulties because they rarely ask an obvious question that may detect or raise awareness about counterfeits: "Where were your drugs purchased?"[185]

Severely exacerbating the problem is that detecting counterfeit, adulterated, or diverted drugs is an immense challenge from a practical forensics perspective. Hints and evidence may be simply unavailable since the medication packaging is thrown away, the patient's body metabolizes the material, and because laboratory tests are normally not available to expose counterfeit medicines. This reality makes forensic investigations on where, how, and what occurred in circumstances of potential fake drugs difficult, if not impossible.[186] Therefore, detecting counterfeit medicines in a patient and provider culture of limited suspicion, and in a market with high quality fakes, is an extremely significant challenge. This circumstance makes counterfeit drug production and sale the perfect crime.[187]

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[183] *See id.* at 290.

[184] This situation is similar to patients dying without knowing they had a treatable illness. *See id*. at 289.

[185] This question may not detect all fake drugs. Patients may also be reluctant to disclose that medicines were bought from a suspect source such as the Internet and/or a foreign country. *See id.* at 289. This may be due to embarrassment or stigma associated with a particular disease state or frustration with access to the care desired; *see also* Jim Thomson, *Stigma? What Stigma?*, E-HEALTH INSIDER, Sep. 6, 2005, http://www.ehiprimarycare.com/comment_ and_analysis/100/stigma_tcq_ what_stigma_tcq (last visited Jan. 31, 2008). However, it does provide an opportunity to educate and raise awareness about the issue.

[186] *See* Bryan A. Liang, *Regulating Follow-On Biologics*, 44 HARV. J. ON LEGIS. 363, 383 (2007).

[187] *See* Liang, *supra* note 8, at 290. Indeed, in one counterfeit case of record, only 10% of the fake drug was recovered, and it is estimated that the 90% that was not was thereby used and undetected by 25,000 HIV and cancer patients. *Id.* at 289 n.75.

1. An Important Note

It is important to note an additional factor. As problematic as the examples of patients encountering counterfeit medicines and the challenge of detection are, what is of even greater concern is that the actual amount of fake drugs found by patients, medical providers, and authorities is highly limited. Counterfeits are manufactured by the thousands, not merely one at a time and then placed into the market. Hence, for each report of a detected counterfeit drug, countless other counterfeits and other batches circulating within and across supply chains go uncounted and undiscovered—while their profits inure to those who would prey upon the sick and vulnerable.

IV. POLICY FAILURES

A. Safety Ignoring Price

Safety efforts to ensure a robust and closed distribution system for counterfeits generally focus on pedigree. Closely allied with this is electronic technology for tracking and tracing drug supplies.

Pedigree for drugs has an extensive history. Originally, the Prescription Drug Marketing Act of 1987 ("PDMA"),[188] modified by the Prescription Drug Amendments of 1992,[189] established requirements to track drugs to "prevent the introduction and retail sale of substandard, ineffective, and counterfeit drugs in the U.S. supply chain."[190] As part of these laws, requirements for a drug pedigree were created. A drug pedigree, for legal purposes, "is a statement of origin that identifies each prior sale, purchase, or trade of a drug, including the date of those transactions and the names and addresses of all parties to them."[191] However, because of industry concerns, the F.D.A. delayed the implementation of the pedigree requirements several times.[192]

In February 2004, the F.D.A. decided to delay full implementation of the pedigree requirement to December 1, 2006.[193] This decision was made because of the apparent assurance that the

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[188] 21 U.S.C. §§ 331, 333, 353, 381 (2006).
[189] *Id.* §§ 333, 353, 381.
[190] *See* F.D.A., DRAFT COMPLIANCE POLICY GUIDE 160.900: PRESCRIPTION DRUG MARKETING ACT—PEDIGREE REQUIREMENTS UNDER 21 CFR PART 203 (2006), *available at* http://www.fda.gov/oc/ initiatives/counterfeit/cpg.html (last visited Oct. 31, 2007).
[191] *See id.*
[192] *See id.*
[193] *See id.*

industry would move away from paper pedigree records and adopt electronic track-and-trace technology for drugs by 2007.[194] Reality intervened, however, and the F.D.A. recognized that such adoption would not take place as planned.[195] Hence, the F.D.A. indicated that the pedigree requirement would be implemented by December 1, 2006.[196] It noted, however, that it continues to believe that RFID, i.e., electronic radio frequency identification, is the most promising technology for electronic track-and-trace across the drug supply chain, and has issued guidelines to encourage RFID use.[197]

The PDMA requirements for pedigree, however, still have yet to fully go into effect. Because of challenges to the operation of the law on secondary wholesalers, a federal court has issued an injunction prohibiting its requirements from being enforced by the F.D.A.[198]

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[194] *See id.*

[195] *See id.*

[196] *See* F.D.A., F.D.A. COUNTERFEIT DRUG TASK FORCE REPORT: 2006 UPDATE (2006), *available at* http://www.fda.gov/oc/initiatives/counterfeit/report6_06.html (last visited Jan. 30, 2008).

[197] *See id.*; F.D.A., RADIOFREQUENCY IDENTIFICATION FEASIBILITY STUDIES AND PILOT PROGRAMS FOR DRUGS (2004), *available at* http://www.fda.gov/oc/initiatives/counterfeit/rfid_cpg.html (last visited Jan. 30, 2008); F.D.A., DOCKET NO. 2004D-0499, OC 2007269, COMPLIANCE POLICY GUIDE; RADIOFREQUENCY IDENTIFICATION FEASIBILITY STUDIES AND PILOT PROGRAMS FOR DRUGS; NOTICE TO EXTEND EXPIRATION DATE, EFFECTIVE DATE DECEMBER 31, 2008 (2007), *available at* http://www.fda.gov/OHRMS/DOCKETS/98fr/04d-0499-nec0001.pdf (last visited Jan. 30, 2008).

[198] *See* RxUSA Wholesalers, Inc. v. Dep't of Health & Hum. Servs., U.S. Food & Drug Admin., CV-06-5086 (JS) (AKT) (E.D.N.Y. Nov. 20, 2006) (issuing preliminary injunction). The case was primarily decided on the basis of the issue surrounding the concept of "authorized distributors of record," or ADRs. ADRs, who have an "ongoing relationship" with manufacturers, are exempt from passing pedigrees, while "unauthorized" distributors must pass pedigree documentation from the manufacturer onward. *See id.* at 3, 12. Since approximately 90% of drugs are passed by "The Big Three" wholesalers who contract directly with drug manufacturers, this would lead to a circumstance where The Big Three, as ADRs, would not be required to pass pedigree to secondary unauthorized wholesalers; these secondary wholesalers would then not be able to provide pedigree documentation as to where they obtained the drugs. *See id.* at 20. It would therefore be impossible for these secondary wholesalers to fulfill the provisions of the law. *See id.* The court ruled that it is not rational to exclude ADRs from the pedigree requirements since they, too, may have purchased drugs on the open market and that while the regulations require ADRs to obtain pedigree when purchasing, it does not require them to provide it. *See id.* at 23. The court then ordered the injunction. *See id.* at 30. The F.D.A. has appealed the decision. *See* RxUSA Wholesalers, Inc. v. Dep't of Health & Human Servs., U.S. Food & Drug Admin., CV-06-5086, Notice of Appeal (E.D.N.Y. Feb. 1, 2007).

Some of the pedigree requirements are, however, considered by the F.D.A. as operational.[199]

However, the pedigree effort is not a panacea guaranteeing safety. At one level, paper pedigrees will not address counterfeiting concerns. As noted by the National Association of Chain Drug Stores:

> A paper pedigree system is not the answer to counterfeiting problems. … In addition to being costly, tracing a drug pedigree on paper is subject to multiple record keeping failures and fraud. Failure to require ADRs to maintain pedigrees would create a major recordkeeping hole in the pedigree requirement. Worst of all, sophisticated drug counterfeiters would no doubt find it easier to counterfeit a paper pedigree than it is to counterfeit the drugs themselves.[200]

This is particularly important in the context of counterfeiters who have the sophisticated expertise to falsify drugs and drug packaging.[201] Others have also noted that pedigree papers are easily forged, 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.[202] Hence, there is a reasonable focus on using electronic means, rather than paper, to track and trace drugs and assist in securing the drug supply against fakes.

However, current anti-counterfeiting efforts using sophisticated technology such as RFID, as touted by the F.D.A., as well as other technologies such as 2D bar codes, tamper-proof labels, label embossing, holograms, bottle etching, thermo-reactive ink, and DNA markers—all suffer from a fundamental defect: they track only

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[199] These include a pedigree that includes information regarding prior transactions going back to the manufacturer *or* ADR that last sold, purchased, or traded the prescription drugs; pedigrees must still be passed by non-authorized distributors of record (non-ADRs) prior to each wholesale distribution. *See* F.D.A., ADDENDUM TO F.D.A.'S GUIDANCE FOR INDUSTRY: PDMA PEDIGREE REQUIREMENTS—QUESTIONS AND ANSWERS RELATED TO THE PRELIMINARY INJUNCTION ORDERED 12/5/06 IN *RXUSA WHOLESALERS, INC. V. HHS* (2006), *available at* http://www.fda.gov/cder/regulatory/PDMA/PDMA_ addendum.pdf.

[200] *See, e.g.*, NAT'L CHAIN DRUG STORES, COUNTERFEIT DRUG TASK FORCE INTERIM REPORT–DOCKET NUMBER 2003N-0361 (2003), http://www.fda.gov/ohrms/dockets/dailys/03/Nov03/110603/03n-0361-c000022-vol3.pdf (submitted to the F.D.A.).

[201] *Id.*

[202] Robb Miller, *Tracking Papers Won't Help*, USA TODAY, May 30, 2005, *available at* http://www.usatoday.com/news/opinion/editorials/2005-05-30-oppose_x.htm (last visited Jan. 30, 2008).

packaging, not product.[203] Hence, as a single safety solution against counterfeits, they are useless because of the reality of legal repackaging in the gray market and through parallel trade domestically and internationally. Indeed, they may undermine the legitimacy and confidence in any pedigree or authentication system based upon them.[204]

It should be noted in particular that the one technology that the F.D.A. and others have touted as a strategy—RFID—has important weaknesses. These include data standardization issues along the distribution chain, international and hemispheric frequency use issues, ownership of data, readability of tags, costs of scanners and readers, and other concerns.[205] As well, health hazards may be associated with

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[203] Liang, *supra* note 74, at 503-04.

[204] *Id.* at 504-05.

[205] *See id.* at 500-03; *see also* Renee Boucher Ferguson, *F.D.A. to Lift Mandate on Prescription Drug Pedigrees*, EWEEK.com, Nov. 14, 2006, http://www.eweek.com /article2/0,1895,2059260,00.asp (describing the effective use of ultra-high frequency RFID technology at the unit, case, and pallet level for track-and-trace, but also noting issues associated with global standards, privacy concerns, and safe handling of biologics, as well as problems getting case and unit-level read rates that exceed 99%, costs, and the need for improved collaboration across the industry). Many other issues also are involved with efforts to unify a track-and-trace system. At the recent F.D.A. RFID meeting that included industry representatives, several issues arose showing the complexity of using a single RFID infrastructure:

- Pfizer is using RFID for tracking bottles of Viagra, but is not including item serialization.
- States have passed pedigree bills requiring some form of electronic track-and-trace pedigree; yet one does not require RFID use or serialization (e.g., Florida) while another (California), which has not yet been implemented, may include an item-level serialization requirement using RFID.
- Wal-Mart has mandated shipment tracking of drugs using ultrahigh-frequency tags, but manufacturers such as Pfizer have found that high-frequency tags work better.
- The read range of tags and the antenna placement of RFID tags need testing.
- Different frequency tags for ultra-high frequency tags versus high frequency tags require multiprotocol interrogators, i.e., tag readers; yet some companies have already invested in single protocol readers, making any switch expensive.
- Industry representatives apparently are confused about electronic pedigree requirements for RFID.

See Mary Catherine O'Conner, *F.D.A. to Update Its RFID Vision*, RFID JOURNAL, Feb. 10, 2006, www.rfidjournal.com/article/view/2148/1/1; *see also* Patton, *supra* note 83 ("[t]here are also questions about how radio frequency will affect biological

this technology; RFID implanted chips have been reported to be associated with malignant tumors in animals.[206]

It should also be noted that individual states are confusing the issue by promulgating their own requirements for pedigree despite the national nature of drug distribution.[207] Because of the delays in

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products. … [T]he industry still needs to be reassured that their liquid and biological medications won't be affected by RFID tags …." and "'privacy could be the killer issue that seriously limits the potential value of RFID in product tracking…'" (quoting Forrester Research Vice-President Laura Ramos)); Thomas Wailgum, *Tag, You're Late*, CIO MAGAZINE, Nov. 15, 2005, *available at* http://www.cio.com/article/143701 (noting that Wal-Mart's requirements for RFID tags are not cost-effective for companies due to a lack of standards; many industry suppliers of consumer goods will not be able to comply; many companies will merely "slap and ship" by sticking a tag on only a fraction of cases and pallets closest to Wal-Mart distribution centers that do not track product movement; there are multiple vendors who sell RFID tags which will require different reading equipment; radio frequencies act abnormally near certain materials, such as liquids, metals, and porous objects; and many tags are of poor quality, with up to 30% unusable). Even proponents recognize the costs of RFID, although they claim that, in the long run, savings can be realized; *see* Suchira Ghosh, Note, *The R.F.I.D. Act of 2006 and E-Pedigrees: Tackling the Problem of Counterfeit Drugs in the United States Wholesale Industry*, 13 MICH. TELECOMM. & TECH. L. REV. 577, 593-94 (2007).

[206] *See, e.g.*, *RFID Chips Linked to Fast-Growing Cancer*, DAILY TECH, Sept. 10, 2007, http://www.dailytech.com/RFID+Chips+Linked+to+FastGrowing+Cancer/article8796.htm; Todd Lewan, *Chip Implants Linked to Animal Tumors*, WASH. POST, Sept. 8, 2007, *available at* http://www. washingtonpost.com/wp-dyn/content/article/2007/09/08/AR2007090800997_pf.html; *see also* Junko Yoshida, *RFID Struggles in Battle Over Bogus Drugs*, EE TIMES, Oct. 1, 2007, http://www.eetimes.com/ news/latest/showArticle.jhtml?articleID=202102924 (reporting RFID challenges in the context of technology issues and politics).

[207] *See, e.g.*, Gary Messplay & Colleen Heisey, *PDMA and State Pedigree Activity: Will States Advance E-Pedigree Programs?*, CONTRACT PHARMA, June 2007, http://www.contractpharma.com/ articles/2007/06/fda-watch; *see also* Matthew B. Van Hook, *Securing the Global Supply Chain: Evolving Federal/State Law—Prescription Drug Distribution, Counterfeit, Pedigree Requirements, and the Internet*, 878 PLI/PAT. 909, 913 (2006) (noting "the PDMA [pedigree requirements have] been further undermined by growing leaks in the closed system from the Internet, mail order and other forms of importation, as well as calls … in the states (out of concerns related to drug costs) to override or ignore import restrictions."). Further, Van Hook notes:

> [S]tate legislatures have convened hearings on the horrors of drug counterfeit and the need to tighten up the state's regulation of the domestic distribution system (in order to promote consumer protection). Many of those same legislatures—sometimes even the same committees—are also holding hearings on proposals to open up that very system to counterfeit by dismantling or impairing drug import controls (but with a different goal in mind, promoting

federal pedigree requirements, seventeen states have adopted their own pedigree requirements while twenty-one others are considering them.[208] What this means is that "it is important for all pharmaceutical manufacturer partners to understand and prepare for the likelihood of individual states adopting legislation and developing individual rules and regulations regarding drug product pedigrees and the potential conflicts that may arise among these disparate pedigree requirements."[209] Such a circumstance results in multiple requirements for pedigree across states, limited potential for a unified system, and even greater confusion as to what is legally required—and what can be effective in deterring counterfeits.

Of course, the efforts to ensure security of the supply chain are laudable. Technology can be part of a solution to detect counterfeits and establish a legitimate pedigree.[210] But even with the development of these fascinating and important technologies, interesting but limited as they are,[211] these efforts unfortunately do little to promote access to authentic drugs at a price vulnerable patients can afford.

First, as noted by J. Alan Cates, a consulting fraud prevention specialist and former State of California Fraud Prevention Bureau

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> consumer savings). Unfortunately, these differing agendas represent real, as opposed to merely apparent, public policy inconsistencies. Some states are now raising the risks faced by their citizens, by encouraging their citizens to flaunt federal law and F.D.A. protections by buying foreign drugs (and at their own risk). Other states have actually passed legislation to allow the licensing of foreign pharmacies.

Id. at 933.

[208] *See* Messplay & Heisey, *supra* note 207.

[209] *See id.*

[210] *See* Liang, *supra* note 74, at 516-17.

[211] *See* Bunker, *supra* note 52, at 494:

> Because the manufacture of this illegal merchandise has grown so rapidly, technological developments designed to impede counterfeiting have struggled to keep up. Pharmaceutical companies have begun to investigate the use of micro-tags and enhanced packaging in an effort to track and verify the shipment and sale of goods throughout the world. … Even with the advent of new technology and more stringent laws, there is a new and substantial threat of counterfeit drugs entering the once safe and relatively secure market in the United States. In addition, demand for "cheap" drugs, technological innovation, and huge profits make it unlikely that the counterfeiting of medicines will soon, if ever, be under control.

Id.

Chief, "[t]he F.D.A.'s recent decision to use [RFID] tags to track drug shipments from manufacturer to major wholesalers may dampen diversion of legitimate drugs. However, the real threat is not legitimate—but counterfeit drugs."[212] As noted previously, in general, patients driven to alternative markets for their drugs are not engaged in the traditional drug distribution system, nor are the counterfeiters who sell to them. Hence, all the pedigree and/or track-and-trace technology in the world in the legitimate distribution chain may not benefit those who have moved into these other channels of distribution to sell and buy drugs.

Second, these extensive efforts to secure the supply chain for legitimate drugs do not address the price issue that drives patients away from the shored-up, technologically laden supply chain. Indeed, if these patients were limited to the traditional supply chain for their drugs, they would be priced out of the market and would have no access at all. Hence, the protections put into place have no usefulness for them unless price is taken into account allowing them to access the market with legitimate distributors selling authentic goods.

B. Price Ignoring Safety

The key policy effort to promote access to pharmaceuticals by addressing price is foreign drug importation.[213] This effort would allow commercial and consumer importation of drugs marketed in other countries. The federal government, particularly under the Pharmaceutical Market Access and Drug Safety Act of 2007 and its earlier iterations,[214] as well as states acting independently through Internet purchasing programs, have looked to foreign sources that have cheaper drug prices to address the access issue.[215] These efforts would allow commercial and personal importation of drugs, as well as individual purchases through state Internet websites that connect

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[212] *See* J. Alan Cates, *F.D.A.'s Placebo for Counterfeit Drugs*, FRAUD PREVENTION INST., www.fraudpreventioninstitute.org/pdf/FDAsPlacebo.pdf.

[213] *See, e.g.*, Pharmaceutical Market Access and Drug Safety Act of 2007, S. 242, 110th Cong. (2007), *available at* http://frwebgate.access.gpo.gov/cgi bin/getdoc. cgi?dbname=110_cong_bills&docid =f:s242is.txt.pdf.

[214] *See id.* This bill is substantively similar with previous leading federal efforts; *see, e.g.*, Pharmaceutical Market Access and Drug Safety Act of 2005, S. 334, 109th Cong. (2005); Pharmaceutical Market Access and Drug Safety Act of 2004, S. 2328, 108th Cong. (2004). These proposals are, and have been, the primary policy efforts employing importation, with the greatest number of co-sponsors and bipartisan support.

[215] *See, e.g.*, Liang, *supra* note 8, at 296 (noting state efforts), 298-307 (reviewing the Pharmaceutical Market Access and Drug Safety Act of 2005, S. 334, 109th Cong. (2005)).

patients to foreign online sellers.[216] Pharmaceutical firms would be prohibited from discriminating against sellers who will participate in the importation program.[217] Internet sales and state programs employing their use have been addressed earlier,[218] and hence the focus here is on federal importation efforts.

With respect to the federal effort, consumers would be permitted to purchase drugs from countries such as Australia, Canada, the E.U., Japan, New Zealand, and Switzerland.[219] This list can expand to include any country that has statutory or regulatory requirements or regulations that include a review of safety, efficacy, good manufacturing processes, adverse event alert mechanisms, and rules on labeling and promotion.[220] The Secretary of Health and Human Services would be required to expedite addition of countries for personal importation if Canada acts to limit or prohibit drug exports to the U.S.[221]

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[216] *See id*.

[217] *See* Pharmaceutical Market Access and Drug Safety Act of 2007, *supra* note 213, at 74. Under current law, pharmaceutical manufacturers would be allowed to claim patent infringement if a drug is sold for or to a foreign entity that is then brought into the U.S. for resale. However, the Pharmaceutical Market Access and Drug Safety Act of 2007 would overrule that policy. *Compare* Jazz Photo Corp. v. Int'l Trade Comm'n, 264 F.3d 1094 (Fed. Cir. 2001), *with* Pharmaceutical Market Access and Drug Safety Act of 2007, *supra* note 213, at 91.

[218] *See supra* notes 155-181 and accompanying text (discussing issues with Internet drug purchasing and state importation programs).

[219] *See* Pharmaceutical Market Access and Drug Safety Act of 2007, *supra* note 213, at 9-12. Note that the bill would allow "bioequivalent" versions of the particular drug to be imported. However, the international definitions of the term are not standard. *See* Liang, *supra* note 8, at 303.

[220] *See* Pharmaceutical Market Access and Drug Safety Act of 2007, *supra* note 213, at 9-12.

[221] *See id*. at 104. Canada has expressed concern regarding U.S. importation efforts of Canadian drugs. Indeed, Canadian Minister of Health Ujjal Dosanijh stated that Canada does not wish to be America's drugstore. *See* The Honourable Ujjal Dosanijh, Can. Minister of Health, Health in a Global Society: A Canadian Perspective, Address at Harvard Medical School, Cambridge, Mass. (Nov. 10, 2004), http://www.hc-sc.gc.ca/ahc-asc/minist/health-sante/speeches-discours/2004_11_10_e.html (last visited Aug. 2, 2007). Patient groups and pharmacists in Canada are calling for regulations to stop the export of prescription drugs and for more oversight of Canadian Internet pharmacies, of which 95% of the business is to the U.S. These groups are concerned that unrestricted sales of Canadian supplies may result in shortages for drugs and higher prices for them—a claim supported by economic analysis. *See Pharmacists Fault Maine Drug Reimportation Plan*, MAINETODAY.COM, Mar. 31, 2005, http://business.mainetoday.com /news/050331.drugs.shtml (last visited Aug. 2, 2007) ("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)); Aidan Hollis & Peter Ibbott, *How Parallel Trade Affects Drug Policies and Prices in*

The federal effort would require domestic commercial importers and foreign exporters to register with the Department of Health and Human Services.[222] It would solicit 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.[223] The Secretary of Health and Human Services would have only ninety days to approve or disapprove the registration.[224]

In addition, the federal bill would require drugs obtained for U.S. consumer use to have a pedigree statement to track, trace, and verify its source and identity.[225] Violations of this provision are not associated with any criminal provisions, but instead would be based on contractual accountability between the parties, for example incentivizing through potential breach of contract actions.[226] Additional security provisions include "anti-counterfeiting or track-and-trace technologies, taking into account the economic and technical feasibility of those technologies."[227] The Secretary of Health and Human Services would be required to mandate the use of standardized anti-counterfeiting or track-and-trace technologies within one year and additional security features on the drug packaging within eighteen months of passage.[228] These provisions would not be required for drugs coming directly from the manufacturer.[229] Internet sales would be allowed if requirements regarding identification of the entity, its location, and its licensure are listed on the website, so long as the site mandates a valid prescription, among other requirements.[230] Banking entities may not allow individuals who place an unlawful importation

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Canada and the United States, 32 AM. J.L. & MED. 193 (2006) (describing how drug importation will increase Canadian drug prices, result in price discrimination there, and may result in shortages for Canadian citizens); Todd A. Rosenfield, *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 U.S. consumers may result from importation).

[222] *See* Pharmaceutical Market Access and Drug Safety Act of 2007, *supra* note 213, at 12, 16.

[223] *See id.* at 14. If the Secretary determines that an importer or exporter has violated this section, he/she may suspend the entity's registration. *See id.* at 20.

[224] *See id.* at 18.

[225] *See id.* at 23-24.

[226] *See id.* at 15.

[227] *Id.* at 27.

[228] *See id.* at 113-15.

[229] *See id.* at 30.

[230] *See id.* at 115-19. The bill also would utilize the National Clearinghouse on Internet Prescribing operated by the Federation of State Medical Boards to identify rogue Internet sellers. However, the Federation had no knowledge of this role in previous iterations of the bill. *See* Liang, *supra* note 8, at 307 n.186.

request to an unregistered foreign pharmacy to have those transactions put through or paid, regardless of the form of the request (e.g., by mail, phone, fax, or the Internet).[231]

The bill requires that foreign firms subject themselves to inspections as a condition to participate in the importation program.[232] The Secretary of Health and Human Services would assign "[one] or more" employees to inspect randomly, "not less than [twelve] times annually" foreign exporting entities.[233] The number of exporters to be inspected in the first year would be a minimum of 600 (twelve inspections/year with a minimum of fifty exporters).[234] The minimum inspections would rise to at least 2,400 in the second year (twelve inspections for a minimum of 200 exporters).[235] Subsequent growth would require a minimum of 300 additional inspections per year (twelve inspections for at least twenty-five additional exporters).[236] Commercial entities would be required to give eight-hour to five-day advance notice as to the shipment of drugs under the bill's provisions.[237] Funding would be through user fees.[238] It appears that the F.D.A. would be the primarily responsible agency for implementation of the bill's provision since it would receive the fees.[239]

Despite a substantive body of evidence that suggests that this form of importation would do little to address the issue of high prices for U.S. patients, since middlemen would garner most of the profits,[240]

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[231] *See* Pharmaceutical Market Access and Drug Safety Act of 2007, *supra* note 213, at 129-32.
[232] *See id.* at 25.
[233] *Id.* at 26-27, 31.
[234] *See id.* at 93.
[235] *See id.* at 93-94.
[236] *See id.* at 94.
[237] *See id.* at 28-29.
[238] *See id.* at 32, 37, 41, 99-100.
[239] *See id.* at 36.
[240] *See, e.g.,* U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 48, at xii-xiii. 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? (2004), *available at* http://www.cbo.gov/ftpdocs/54xx/doc5406/04-29-PrescriptionDrugs.pdf. Parallel importation experience in Europe indicates similar pricing dynamics, with the parallel traders gaining the benefits of this 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 Sch. of Econ., Working Paper, 2004), executive summary *available at* http://www.lse. ac.uk/collections/LSEHealthAndSocialCare/pdf/Workingpapers /executivesummary.pdf. It also appears that any savings that is occurring now is being reduced annually, potentially on the basis of Canadian suppliers seeking economic rents from U.S. consumers. *See* Associated Press, *Americans Save Less*

and that it may lead to a negative economic trade-off for the U.S.,[241] policymakers continue pushing this strategy to address the problem of price and its relation to access. Unfortunately, it is fraught with safety challenges.

First, "safe" countries, such as Canada, the U.K., and other E.U. countries, are subject to drugs coming from questionable source countries such as China and India, as well as other countries such as those in Eastern Europe, Russia, and Turkey. As seen previously, the E.U. has become increasingly awash in counterfeits itself.[242] Indeed, Canada imports drugs from roughly eighty countries, including those within the E.U. and those with the highest incidence of suspect drugs,[243] and has experienced deaths associated with fake medicines.[244]

Buying Canadian Drugs, WALL ST. J., Jan. 5, 2005 (Eastern ed.), *available at* http://proquest.umi.com/ pqdweb?did=774108921&sid=1&Fmt=3&clientld=15023&RQT=309& VName=PQD (describing study by PharmacyChecker.com showing a drop in price discounts between Canada and the U.S. from 38% in 2003 to 29% in 2004). Further, it is difficult to assess actual price differentials because of the varying methodologies being used to assess it, including review of prices charged by manufacturers, consumer prices, insurer/HMO prices, government prices, and the particular drugs specifically 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 STUD. L. REV. 135, 143-44 (2005). Other factors, such as the litigation system differences between countries, may also play a role. *See id*. at 148-50. However, using an empirical pricing model, economists have found that benefits associated with price controls will not inure to patients. *See* John A. Vernon et al., *The Economics of Pharmaceutical Price Regulation and Importation: Refocusing the Debate*, 32 AM. J.L. & MED. 175 (2006); Hollis & Ibbott, *supra* note 221 (describing how drug importation will increase Canadian drug prices as well as U.S. prices, result in price discrimination in Canada, and may lead to shortages for Canadian citizens).

[241] *See, e.g.*, John A. Vernon et al., *The Internet and Pharmaceutical Importation: Economic Realities and Other Related Issues*, 16 ALB. L.J. SCI. & TECH. 545 (2006) (concluding that a large-scale importation policy, if successful in lowering U.S. drug prices to Canada and E.U. prices, will likely cost the domestic economy between $4.0 and $11.3 trillion as a result of forgone or delayed pharmaceutical innovation, and the benefits from lower, imported drug prices, assuming such cost savings can be passed on to U.S. consumers and not fully or partially absorbed as profit for the importing and exporting firms, are likely to be much smaller than the costs of reduced innovation).

[242] *See supra* notes 54-71 and accompanying text (reviewing the E.U. experience with counterfeits).

[243] *See, e.g.*, 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 China and India).

[244] *See* Liang, *supra* note 8, at 296 (reporting imported counterfeit cardiac drugs leading to patient deaths and pharmacist charged with selling fakes).

As well, another open hole noted previously[245] is that domestic safety laws do not apply if drugs are not for domestic consumption. For example, drugs from, say, China and India, earmarked for U.S. citizens that pass through Canada are unregulated by Health Canada because they are not intended for Canadian distribution to Canadian citizens.[246] Indeed, Canadian pharmacies have been found to have been selling unapproved drugs that originally come from Mexico to U.S. citizens.[247]

This trend is likely to continue, and its concomitant risks of unregulated drug imports are likely to expand. There has been a tremendous increase in imported drugs into Canada from questionable sources, including "significant increases in Canadian imports of pharmaceuticals from Singapore (30%), Ecuador (198%), China (43%), Iran (2,753%), Argentina (221%), South Africa (84%) and Thailand (52%) between September 2002 and September 2003."[248] These countries are not inspected, nor do they have a mutual recognition agreement on current Good Manufacturing Practice ("cGMP") with Canada and therefore their products cannot be sold to Canadian citizens.[249] Yet "Canadian law does not require the country to regulate or guarantee the safety of prescription medicines manufactured in foreign nations and transshipped through Canada to the United States."[250]

As well, provisions in the importation bill that would allow countries with statutory or other rules that provide for desirable characteristics of a drug regulatory scheme to import to U.S. citizens are trumpeting form over substance. Countries like China, India, and Russia, as well as a host of other countries, could fall within this category,[251] yet are high-risk sources of counterfeit medicines.

As noted earlier, anti-counterfeiting and track-and-trace efforts, as mandated by the bill, are no panacea for ensuring safety of the drug supply.[252] The talents of counterfeiters to make products, as well as holograms and package inserts, make accurate counterfeiting of

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[245] *See supra* note 165 and accompanying text (noting domestic drug safety laws do not apply to transshipped goods).
[246] *See* Liang, *supra* note 8, at 297.
[247] *See id*.
[248] *See Sharp Increase in Foreign Prescription Drugs Entering Canada*, BUS. J. ONLINE (Ohio), Apr. 9, 2004, http://www.business-journal.com/LateApril04/CanadaDrugs.html.
[249] *See id*.
[250] *See id*.
[251] *See* Liang, *supra* note 8, at 299 n.137.
[252] *See supra* notes 200-212 and accompanying text (reviewing limitations to safety solutions focused on technology).

pedigree documentation very likely.[253] Technology-based efforts, in an effort to secure the safety of medications, have also shown their weakness and are not ready for prime time. Ironically, the pressure to put such unready devices into place under the bill's requirements may create errors and harm in the domestic market, where large wholesalers stock 75,000 products and deliver greater than two million items *per day*.[254] Finally, with respect to pedigree, enforcement of these requirements by the threat of a contract-based civil lawsuit would likely have little impact on the bad faith manufacturer and purveyor who receives its share of the spoils.

In addition, funding of the entire enterprise through user fees is very troubling. Using registration and inspection fees to fund F.D.A. efforts is similar to requiring user fees for F.D.A. drug review. This scrutiny paid for by the scrutinized has been the subject of much criticism, and would make the reviewers completely supported by the entities they are responsible for inspecting, creating a host of problematic issues.[255]

Moreover, continuing to allow Internet sales of drugs is highly problematic. Because this source is a tremendous challenge for law enforcement, and limited requirements are put into place by the bill, this would likely result simply in fictitious and unscrutinized information being placed on the thousands of web pages advertising drugs[256] while inappropriate online sales continue. Further, relying on banking and financial institutions to police Internet sales is unrealistic and certainly not within their traditional skill sets. Indeed, these institutions have in the past resisted engaging in or assisting in investigation of parties involved in an Internet transaction without a subpoena.[257]

Of great concern within the bill is the reliance upon F.D.A. inspection and close review of foreign entity activities. These

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[253] *See* Liang, *supra* note 8, at 300-01.

[254] *See* Robert P. Giacalone, *Drug Wholesaling and Importation: Challenges and Opportunities?*, 36 CAL. W. INT'L L.J. 65, 67 (2005).

[255] *See* Liang, *supra* note 8, at 302. User fees can result in conflict of interest issues as well as Congressional budget cuts. *See id.* For further discussion of the F.D.A. and the problem of pharmaceutical drug application fees, *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 Drugs-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.

[256] *See supra* notes 161-176 and accompanying text (discussing challenges of regulating Internet drug sales).

[257] *See* GOV'T ACCOUNTABILITY OFFICE, *supra* note 142, at 32-33.

provisions in particular illustrate the minimal policymaker understanding of current safety infrastructure weaknesses of U.S. drug regulation.

Resources for safety efforts by the F.D.A. are scarce at best. Take, for example, the importation of drugs through the U.S. mail. The U.S. Department of Health and Human Services' report analyzing this issue found that there were only 16.9 full-time F.D.A. employees responsible for covering *all* international mail facilities in the U.S. to detect imported counterfeit medications, and this was not their only duty.[258] To provide a context for this number, it has been estimated that roughly *20 million* packages containing drug products enter the U.S. annually through the U.S. mail.[259] Hence, it is ludicrous to assume that these 16.9 inspectors can give anything more than a passing glance to these 20 million mail packages.

As might be expected, then, under current policy, packages not processed or inspected by the F.D.A. by the end of each work day are passed on to be delivered to the recipient by the U.S. Postal Service.[260] As a result, the F.D.A. has estimated that 9,000 to 10,000 packages containing drugs per week are not inspected.[261] However, this is likely a severe underestimate because both Customs and Border Protection ("C.B.P.") officials and F.D.A. inspectors rely on a shipper's description of the contents of packaging when considering an inspection:[262]

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[258] *See* U.S. DEPT. OF HEALTH & HUMAN SERVS., *supra* note 48, at 56 fig. 5.3. Note that this figure does not include 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*, PROC. NINTH ANN. ASHP MGMT. CONF. FOR LEADERS IN HEALTH-SYSTEM PHARMACY 8 (Oct. 18-19, 2004), http://www.ashp.org/practicemanager/LeadershipDev/2004LeadershipSummary.pdf. Shepherd also indicates that there has been a 1000% increase in the number of drug packages destined for U.S. customers from 2003 to 2004. *See* Shepherd, *Drug Quality*, *supra* note 51, at 79.

[259] *See* Shepherd, *Drug Quality*, *supra* note 51, at 80.

[260] *See* GOV'T ACCOUNTABILITY OFFICE, *supra* note 142, at 21.

[261] *See id.* at 22.

[262] *See id.* at 26. Note that:

> small mail shipments [at international mail facilities] are excluded [from F.D.A. formal foreign inspection eligibility] because they are generally of a lower value and do not reach the threshold of a formal entry. The international mail system remains an un-automated, paper-based system and packages coming through it are not routed through F.D.A.'s electronic screening system. They are off-line and virtually unevaluated for risk, unless a wary, experienced Customs official targets a package for further F.D.A.

> C.B.P. and F.D.A. officials [indicated] that there are no assurances that the shipper's description of the contents is accurate. The F.D.A. officials at the [mail] carrier facilities … told us that if a package contains a prescription drug but is inaccurately described, it would not likely be inspected by F.D.A. personnel.[263]

Further, beyond efforts to assess drugs entering into this country through the mail, the F.D.A.'s ability to inspect products made or processes used by foreign entities, either at our border or in their countries, is highly limited. Even with some additional funding under the bill, its requirement of hundreds to thousands of additional inspections of exporters is highly unrealistic and illustrates a lack of comprehension regarding the current state of the F.D.A. foreign inspection program.

Currently, the F.D.A. is already responsible for overseeing the safety and effectiveness of drugs marketed in the U.S., both when manufactured domestically or in foreign facilities.[264] These foreign

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> review. However, even in those situations, F.D.A. can review only a very small fraction of the packages targeted by Customs.

Statement of Benjamin L. England, before the Subcomm. on Oversight & Investigations, Comm. on Energy & Commerce, U.S. House of Representatives 4, Nov. 1, 2007, *available at* http://energycommerce.house. gov/cmte_mtgs/110-oi-hrg.110107.England-Testimony.pdf. In addition, generally, any shipment with less than a $2000 value is "essentially given a free pass as an informal Customs entry." *See* Statement of Carl R. Nielsen, *supra* note 28, at 12.

[263] *See* GOV'T ACCOUNTABILITY OFFICE, *supra* note 142, at 26.

[264] *See* GOV'T ACCOUNTABILITY OFFICE, *supra* note 34, at 4. Multinational drug companies often contract to manufacture drugs overseas for the U.S. markets. The F.D.A. is responsible for inspecting these manufacturing facilities. This includes the "manufacture, preparation, propagation, compounding, or processing of a drug." *See* 21 C.F.R. § 207.3(a)(8) (2007). The F.D.A. carefully assesses the quality of the drugs as a function of purity, strength, and quality, and ensures these drugs are manufactured in sanitary conditions using Good Manufacturing Practices for safety purposes. As noted by William K. Hubbard, former Associate Commissioner of the F.D.A.,

> drugs are cautiously tested, first in animals, then in humans, and approved by F.D.A. only if their medical benefits outweigh any risks they pose. Once approved for marketing, a drug must be manufactured under specific controls mandated by F.D.A.—known as Good Manufacturing Practices. These include requirements that active ingredients of the drug be of a prescribed purity, strength and quality; that the drug be made in well controlled, sanitary conditions; that its labeling and packaging be equally well controlled; and that laboratory tests of the drug be performed routinely using well established scientific methods and

facilities must register with F.D.A., and, in an effort to ensure the safety and quality of these imported drugs, the F.D.A. "is responsible for inspecting foreign establishments whose products are imported into the United States. The purpose of these inspections is to ensure that foreign establishments meet the same manufacturing standards for quality, purity, potency, safety, and efficacy as required of domestic establishments."[265]

Yet, at the outset, there are tremendous problems with F.D.A. inspections of foreign-made drugs. First, there are more than 300,000 foreign manufacturers of all F.D.A.-regulated products, which are distributed among more than 200 countries and enter through roughly 300 Customs ports of entry.[266] There are only roughly 200 inspectors that cover all of these ports.[267] Hence, the likelihood of an imported drug being sampled at all at official U.S. border entry points is exceedingly low. For example, in 2006, of the millions of drug shipments arriving from foreign countries last year, only 340 were taken for laboratory testing.[268] Decisions as to whether to allow a shipment to enter into the U.S. are not based on or related to conditions of product manufacturing that impact drug safety.[269] This process simply "will not, [and] can not, readily detect shortcomings in manufacturing conditions that could cause the imported products to be unsafe."[270]

Second, and of equal or greater concern, despite the growing amount of drugs and/or their active pharmaceutical ingredients coming into this country,[271] the regulatory function and effectiveness of the

> properly calibrated equipment to confirm that the drug is always produced in the form approved by the F.D.A..

Statement of William K. Hubbard, *supra* note 25, at 2.

[265] *See* GOV'T ACCOUNTABILITY OFFICE, *supra* note 34, at 4.

[266] *See* Statement of Carl R. Nielsen, *supra* note 28, at 14-15. These are in distinction to materials entering through U.S. mails. *See* Shepherd, *Drug Quality*, *supra* note 258 and accompanying text (describing problems with inspecting drugs entering the U.S. mail system).

[267] *See* Statement of Carl R. Nielsen, *supra* note 28, at 15.

[268] *See* Statement of William K. Hubbard, *supra* note 25, at 6.

[269] *See* Statement of Carl R. Nielsen, *supra* note 28, at 11. This is often due to the problems with information inspectors have access to in poorly coordinated databases. *See id.* at 11-12.

[270] *Id.* at 9.

[271] It is estimated that at least 80% or more of finished dosage form drug or active pharmaceutical ingredient will be from foreign sources by the end of the decade. *See* Statement of William K. Hubbard, *supra* note 25, at 6. This also creates other issues beyond safety. Reliance upon foreign countries may create a terrorism preparedness issue. For example, if a bioterrorist attack involving anthrax were to occur in the U.S., it would be difficult if not impossible to obtain the necessary treatments, generally ciprofloxacin and doxycycline, once U.S. stockpiles are quickly exhausted,

because most of the manufacturing for the active ingredients of the drugs is now located in China and India. *See* Tim Johnson, *Pharmaceutical Drugs Made in China May Mean Trouble for U.S.*, KANSAS CITY STAR, Dec. 5, 2007, *available at* http://www.kansascity.com/105/story/391581.html (last visited Dec. 5, 2007). This may also make drug access subject to political concerns, whims, and use as a weapon. *See id.* (discussing access to, for example, cholesterol drugs if a conflict occurs between China and Taiwan). It should be noted that drugs have been considered a tool by terrorists to kill U.S. citizens. For example,

> In addition to providing a way for unscrupulous enterprises to obtain massive profits by distributing phony, high–priced drugs, the vulnerabilities in the system provide a way for terrorists to target our citizens. One frightening and widely discussed scenario, among dozens of possibilities of how terrorists might exploit our vulnerabilities in this area, involves a deliberate anthrax "scare" in order to trigger a run on Cipro[floxacin], the antibiotic used for fighting the anthrax poison. A phony, deadly version of this medicine, having already been injected without detection into the nation's pharmaceutical stream by terrorists, would then cause thousands more deaths. Baz Mohammad, a Taliban-linked narco-terrorist who was recently extradited from Afghanistan, defends a "Jihad" of taking Americans' money at the same time the drugs we are paying for kill us.

See Liang, *supra* note 74, at 517 (quoting Rep. Mark Souder, Chairman, Subcomm. on Criminal Justice, Drug Policy & Human Res.). In this situation, the result is the best of all worlds for the terrorist: the West funds its own demise.

Finally, simply having one drug come from one source country may be problematic if that source has poor quality products. For example, a Chinese government-owned pharmaceutical manufacturer is being investigated after hundreds of leukemia patients who took its drugs became paralyzed or otherwise harmed. *See* Jake Hooker & Walt Bogdanich, *Tainted Drugs Tied to Maker of Abortion Pill*, N.Y. TIMES, Jan. 31, 2008, *available at* http://www.nytimes.com/2008/01/31/world/asia/31pharma.html?_r=2&hp&oref=slogin&oref=slogin (last visited Feb. 5, 2008). This company has already had problems with fake or tainted drugs being discovered and stopped from entering the U.S. in the past. Unfortunately, it is the only U.S. supplier of mifepristone, also known as RU-486, an abortion medication. *See id.*

Another recent example of vulnerabilities associated with a single source country involves heparin, where "[a] Chinese factory that has not been inspected by the Food and Drug Administration [was] the source for the active ingredient of a critical blood-thinning drug whose production was suspended this week after 350 patients reported ill effects from it. … At least four people died after being given the drug, heparin."; *see* Gardiner Harris, *Chinese Factory Linked to Drug Under Inquiry in U.S.*, N.Y. TIMES, Feb. 14, 2008, *available at* http://www.nytimes.com/2008/02/14/business/ worldbusiness/14heparin.html?_r= 1&ref= business&oref=slogin. This estimate has been raised to nineteen deaths and 785 adverse events. Justin Blum, *Heparin Will Be Blocked at Border Unless Tested*, BLOOMBERG.COM, Mar. 14, 2008, *available at* http://www.bloomberg.com/apps/news?pid=newsarchive&sid=amOYUH69fc.0 (last visited Mar. 17, 2008). China is the largest source of heparin in the world, amongst other drugs; *see* Thomas M. Burton et al., *Heparin Probe Finds Ties to Chinese Plant*, WALL ST. J., Feb. 15, 2008, at B1. Apparently,

international F.D.A. foreign inspection program—the strategy employed by the importation proposal to ensure safety—is and has been poor at best.[272] For example, budgeting constraints lead to only 1,000 F.D.A. inspections on foreign soil each year—of which only one-third to one-half are for pharmaceuticals.[273] Further, F.D.A.

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illustrating the underlying weaknesses of the F.D.A. foreign inspection program, the Chinese plant had not been inspected; the F.D.A. had made a paperwork error, which then led regulators to assume that the production facility had in fact been inspected. *See* Bruce Japsen & David Greising, *F.D.A. Mixed Up Drug Plant Names: Confusion Prevented Chinese Factory Inspection*, CHI. TRIB., Feb. 19, 2008, *available at* http://www.chicagotribune. com/features/lifestyle/health/chi-tue_bloodthinner2.19feb19,1,4564760.story (last visited Feb. 21, 2008). Even with inspections, however, due to the origination of the drug in very small Chinese factories, and the poor documentation of the supply chain in China, the limited regulation of factories as a chemical maker and not drug producer, and additional products that may be made in these facilities (the Chinese factory in this case also makes sausage casings), it may be virtually impossible to determine where quality issues arose. *See* Gordon Fairclough & Thomas M. Burton, *The Heparin Trail: China's Role in Supply of the Drug Under Fire*, Feb. 21, 2008, at A1, A14. Unfortunately, these considerations have led to the recall of heparin by three countries, the U.S., Germany, and Japan, as well as an F.D.A. import alert that requires all heparin from China to be inspected once it reaches the U.S. Marc Kaufman, *FDA Says Contaminant in Blood Thinner Is Nearly Identified*, WALL ST. J., Mar. 15, 2008, at A09, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2008/03/14/AR2008031403484. html?nav=rss_health (last visited Mar. 17, 2008). There are questions as to whether the source of the adverse drug reactions associated with the Chinese heparin were human-sourced or were naturally occurring. *See id.*

[272] According to one former F.D.A. official:

> Eight years ago F.D.A. came before this Committee to answer questions about [the safety risks associated with imported product and specifically the foreign inspection program] based upon the Committee's thorough investigations into a series of imported counterfeit bulk drug cases initiated by F.D.A. in the very early 1990s. The F.D.A.'s foreign drug inspection program, its import programs, and its information technology (IT) systems, which are overburdened with the responsibility of managing data about both, were broken then and, quite frankly, they remain broken today.

Statement of Benjamin L. England, *supra* note 262, at 2.

[273] *See* Press Release: Grassley Delves Further into F.D.A. Review of Foreign-Made Pharmaceuticals, Sen. Chuck Grassley, *available at* http://grassley.senate.gov/public/index.cfm? FuseAction=PressReleases. Detail&PressRelease_id=f2e49d13-1321-0e36-bacd1039b4f797ce&Month= 10&Year=2007 (last visited Nov. 1, 2007) [hereinafter Press Release, Grassley].

Note that, of other F.D.A.-regulated products, such as veterinary drugs, two-thirds are made in China and other developing countries, and only fourteen inspections were performed in 2007, and of tremendous concern is that "perhaps most—dietary supplements are produced in China … and a grand total of two of the foreign manufacturers of supplements received an F.D.A. inspection last year."

inspectors, whose numbers are decreasing,[274] rarely visit purportedly

Statement of William K. Hubbard, *supra* note 25, at 10-11. Note that the F.D.A. is also responsible for ensuring the safety and efficacy of excipients and over-the-counter ("OTC") drugs, which represent additional challenges for the agency. Statement of Benjamin L. England, *supra* note 262, at 9-10 & n.12. With respect to excipients, it should be noted that the poisoning associated with diethylene glycol in Panama and with toothpaste made in China was a result of deficient cGMP practices. *See* Statement of Carl R. Nielsen, *supra* note 28, at 13. With respect to OTC drugs, "[w]eaknesses in F.D.A.'s current regulatory paradigm to ensure safety of imported goods are consistent across all imported regulated goods. This includes oversight of imported pharmaceuticals, [prescription] and OTC alike." *Id.* at 11. Nielsen indicates that inspection of foreign OTC manufacturers "may range into several decades, maybe a [fifty-] years cycle or more. … But in foreign OTC manufacturing, cGMPs are virtually never assessed." *Id.* at 12- 13. Further, since there are no regulatory pre-approval barriers to entry of OTC products, entities formulating these drugs,

> are free to obtain raw materials from any manufacturer and may change suppliers freely and frequently to obtain the lower costs. … The use of unproven or hazardous excipients in the formulations is possible because there currently is no systematic mechanism for detection or prevention of their use in such products.

Statement of John B. Dubeck, before the Subcomm. on Oversight & Investigations, Comm. on Energy & Commerce, U.S. House of Representatives 8-9, Nov. 1, 2007, *available at* http://energycommerce.house. gov/cmte_mtgs/110-oi-hrg.110107.Dubeck-Testimony.pdf. Indeed, compounding the F.D.A.'s problematic inspection of OTC drugs, E.U. authorities also have tremendous challenges in inspecting over-the-counter and generic manufacturers:

> globali[z]ation has caused unprecedented pressure on prices and profit margins and has driven these generic and OTC companies to buy their APIs [active pharmaceutical ingredients] at the lowest cost from plants that have never been inspected by any health authority from the E.U. or the U.S. In 2005, China alone—including European owned sites there—exported 39,700 metric ton[ ]s of paracetamol [acetaminophen]; a 21% increase over 2004 and enough to produce billions of tablets.

Statement of Guido Villax, before the Subcomm. on Oversight & Investigations, Comm. on Energy & Commerce, U.S. House of Representatives 2, Nov. 1, 2007, *available at* http://energycommerce.house.gov/ cmte_mtgs/110-oi-hrg.110107.Villax-Testimony.pdf.

[274] The F.D.A. allocated 149 inspectors to the foreign inspection program in 2002, and will likely cut back to 102 by 2008, with a budget of less than $16 million, significantly lower than the $16.7 million allocated in 2002. *See* SUBCOMM. ON OVERSIGHT & INVESTIGATIONS, STAFF TRIP REPORT, F.D.A. FOREIGN DRUG INSPECTION PROGRAM: A SYSTEM AT RISK 2 (2007), *available at* http://energycommerce.house.gov/cmte_mtgs/110-oi-hrg.110107.StaffTripReport.pdf. Note that funding issues also are putting domestic food safety at risk; the F.D.A. has placed even domestic high-risk food firms on a looser inspection

regulated foreign manufacturers. One source estimates they inspect these facilities only once every eight to twelve years;[275] another indicates that they only inspect 7% of foreign facilities annually and visit them only once every thirteen years;[276] and another estimates that, in a worst case scenario, an inspection would occur only once every thirty years.[277]

Beyond funding issues,[278] inspectors are generally not knowledgeable about the country's political and regulatory climate, nor do they specialize in a particular country or region of the world.[279] Because of the estimated doubling of F.D.A.-regulated imports every five years[280] and the static F.D.A. resources devoted to the safety of

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schedule due to appropriations issues. *See* John Wilkerson, *High-Risk Food Firms Face Fewer F.D.A. Inspections*, INSIDEHEALTHPOLICY.COM, Dec. 13, 2007, http://insidehealthpolicy.com/secure/health_docnum.asp?f=health_2001.ask&docnum=12132007_risk&DOCID=12132007_risk (last visited Dec. 14, 2007). Note, however, that even as this vulnerability is being recognized, a U.S.-China food safety Memorandum of Understanding signed by the countries may ultimately reduce high-risk Chinese export inspections into this country under a food safety certification system in a manner not offered to other countries, such as Canada and Mexico. *See U.S.-China Food Safety Deal Could Give China Preferential Treatment*, FDA WEEK, Dec. 21, 2007, *available at* http://insidehealthpolicy.com/secure/health_docnum. asp?f=health_2001.ask&docnum=FDA-13-51-17&DOCID=FDA-13-51-17 (last visited Dec. 17, 2007).

[275] *See* Andrew Bridges, *Foreign Drug Makers Face Few Inspections*, AP YAHOO NEWS, Nov. 1, 2007, http://news.yahoo.com/s/ap/20071101/ap_on_he_me/fda_foreign_drugs (last visited Nov. 1, 2007). A 1998 GAO report indicated that the F.D.A. could only inspect foreign drug manufacturers once every eleven years. *See* SUBCOMM. ON OVERSIGHT & INVESTIGATIONS, *supra* note 274, at 2. A domestic industry spokesperson estimates that, in fact, foreign manufacturers are visited even less frequently, once every fourteen years. *See* Bridges, *supra*. Note that the F.D.A. is required to inspect domestic manufacturers once every two years under 21 U.S.C. § 360(g), and comes close to meeting this requirement. *See* Statement of Carl R. Nielsen, *supra* note 28, at 6.

[276] *See* GOV'T ACCOUNTABILITY OFFICE, *supra* note 34, at 13. Note that this may be optimistic, because the calculation is based on the assumption that no additional establishments are subject to inspection and inspection data is based on information provided only as of September 26, 2007. *See id.* at 13 n.21. *See also* Statement of John B. Dubeck, *supra* note 273, at 3 (noting, in 2004, the F.D.A. performed cGMP inspections on 55% of domestic facilities, but only 7% of foreign facilities).

[277] *See* Statement of Carl R. Nielsen, *supra* note 28, at 12.

[278] Deeper cultural issues at the F.D.A., coupled with domestic stress on the system, may result in an active ignorance of challenging foreign inspection issues. *See, e.g.*, *id.* at 8 ("There is an F.D.A. culture of not wanting to know there may be more regulatory problems outside the traditional domestic industry because the agency is already strapped with domestic regulatory issues.").

[279] *See* SUBCOMM. ON OVERSIGHT & INVESTIGATIONS, *supra* note 274, at 4. Note also that the F.D.A. inspectors are not provided with health briefings about the country that would identify diseases that pose significant health risks. *See id.*

[280] *See id.* at 2. Indeed,

imported products, the F.D.A. continues to fall further and further behind in its efforts to assess foreign entity activities or develop relevant expertise. As a result, most of these inspections are of companies who are awaiting F.D.A. approval to make new drugs,[281]

> From 1997 to 2002, the number of imports of every kind of F.D.A.-regulated product at least doubled. This year, in 2007, F.D.A. anticipates as many as 18 million commercial lines of entry under its jurisdiction will be imported—representing a second doubling in the sheer number of entry transactions since 2002. F.D.A.'s resources directed at assessing the safety of imported products has remained static throughout the entire time period.

Statement of Benjamin L. England, *supra* note 262, at 4. England further notes that,

> even though roughly half of all F.D.A.-regulated products consumed in the U.S. are either manufactured in whole or in part in a foreign country, as I recall by the summer of 2003 approximately only [seven] out of every 100 dollars spent by F.D.A. regulating products under the Agency's jurisdiction was focused on F.D.A.'s import or foreign programs.

Id. at 4 n.2.

Note that the expansion will likely continue and exacerbate the current challenges in foreign inspections. Even more multinational drug firms intend to set up facilities in countries such as China and India. *See* SUBCOMM. ON OVERSIGHT & INVESTIGATIONS, *supra* note 274, at 5. These two countries represent the largest foreign suppliers of drug ingredients, but are both developing countries with weak regulatory systems over drug manufacturers. *See* Statement of William K. Hubbard, *supra* note 25, at 7. They also have a poor track record; they are the source of dangerous and substandard drugs, and "F.D.A. inspectors have at times found horrendous conditions" in their facilities. *See id*.

Further, it should be noted that many foreign manufacturers register to export to the U.S.—a costless process since it is free—but never do so; they may believe that having the U.S. registration gives a "seal of approval" for their products. *See* Press Release, Grassley, *supra* note 273; GOV'T ACCOUNTABILITY OFFICE, *supra* note 34, at 10. However, the inspection of these facilities is still the responsibility of the F.D.A., draining agency resources from inspecting facilities that actually do manufacture and export products to the U.S. *See* Press Release, Grassley, *supra* note 273.

[281] New prescription drugs, whether they be innovative drugs or new generic forms, must be approved by the F.D.A. before marketing through an application process. *See infra* note 327 (outlining new drug application, biologic license application, and abbreviated new drug application approval process by the F.D.A.). The approval is both manufacturer-specific and product-specific, and includes an assessment of manufacturing location, formulation, source, and specifications of active ingredients, manufacture controls, the container, and labeling. *See* Statement of Andrew C. von Eschenbach, before the Subcomm. on Oversight & Investigations, Comm. on Energy & Commerce, U.S. House of Representatives 2, Nov. 1, 2007, *available at* http://energycommerce.house.gov/cmte_mtgs/110-oi-hrg.110107. vonEschenbach-testimony.pdf. The F.D.A. inspects each manufacturing site identified in these

rather than cGMP inspections to ensure a company's product remains safe after initial F.D.A. approval[282]—the only means to ensure drug safety.[283] Also, under its current infrastructure, the F.D.A. does not routinely verify information provided by foreign manufacturers in registration statements.[284] Yet, analysis of cGMP inspections indicates that foreign firms have significantly greater numbers of violations than domestic firms.[285]

The actual number of foreign manufacturers exporting drugs into the U.S. is also unknown by the F.D.A., with estimates ranging

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applications prior to approving any application to ensure compliance with cGMP at the facility. *See* Statement of John B. Dubeck, *supra* note 273, at 4. However, even limiting itself to these inspections, the F.D.A. often does not manage to inspect every facility for a pre-approval drug application. *See id.* at 4-5.

[282] *See* GOV'T ACCOUNTABILITY OFFICE, *supra* note 34, at 13, 15. The F.D.A. only inspected 341 foreign drug manufacturers in 2006, and, as noted, most were "preapproval inspections" for drugs about to be approved by the F.D.A. for marketing. The number of good manufacturing compliance inspections was limited to "perhaps two dozen or so." *See* Statement of William K. Hubbard, *supra* note 25, at 6-7. However, according to another former F.D.A. official, "Achieving a more appropriate [two to three] year inspection cycle [using low figure of 3,000 foreign drug establishments that should be inspected] would require F.D.A. to conduct approximately 1,250 (on average) foreign surveillance, cGMP inspections per year." Statement of Benjamin L. England, *supra* note 262, at 9.

[283] *See* Statement of Benjamin L. England, *supra* note 262, at 10-11 ("Compliance with F.D.A.'s drug cGMP program is the only (current) framework within which the agency can justify relying upon results obtained from finished product test. … Without an assessment and understanding about the conditions of manufacture within the facility, the finished product test results are anecdotal at best. Such an approach cannot predict, measure, assess, or assure drug safety."); Statement of Carl R. Nielsen, *supra* note 28, at 2. As Nielsen also points out,

> The traditional first and internationally recognized primary method for the [F.D.A.] to ensure drug products are safe and effective after product approval is to conduct current good manufacturing practice (cGMP) inspections to ensure the firms are in compliance with requirements of the current good manufacturing practice regulations (cGMPRs) and conditions promised in the drug applications.

Id. Further, "[f]inished product testing alone is inadequate to ensure a batch of product is safe and effective. … [T]esting alone can not put the quality and safety into the product. It is the manufacturing processes and application of effective quality assurance programs that determine the quality and safety." *Id.* at 4. As well, it has been noted that "[o]nce the safety and effectiveness of a drug has been established, the only assurance that on-going production will yield products with the same assurance of safety and effectiveness is if the products are manufactured in accordance with current good manufacturing practice (cGMP)." Statement of John B. Dubeck, *supra* note 273, at 2.

[284] *See* GOV'T ACCOUNTABILITY OFFICE, *supra* note 34, at 10.

[285] *See* Statement of John B. Dubeck, *supra* note 273, at 5.

from 3,000 to 6,760.[286] Many emerging countries that are entering into the U.S. market have never been inspected.[287]

Indeed, practical realities of foreign inspections not taken into account by importation proposals hinder safety efforts. For example, inspection teams must obtain authorization from the relevant foreign government to enter and inspect the facilities, and the F.D.A. has no ability to mandate or assign inspectors.[288] Further, the F.D.A. has no authority to conduct surprise inspections since they must be announced, often several months ahead of time.[289] In addition, the inspection teams have limited ability to collect drug samples on-site, and often must accept drug samples for analysis that are sent to the U.S. by the manufacturer itself.[290]

Reflecting the strain on the system, F.D.A. databases are also in poor shape. The more than a dozen[291] F.D.A. databases are different, incompatible, and incomplete regarding recording information and tracking what drugs and drug ingredients are imported, as well as what companies are certified to import drugs and which firms have been inspected.[292] This lack of accurate data results

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[286] *See* GOV'T ACCOUNTABILITY OFFICE, *supra* note 34, at 11.

[287] *See* Press Release, Grassley, *supra* note 273, at 9 (noting Bangladesh as a specific example of a country not inspected).

[288] Since F.D.A. foreign inspection teams are voluntary, the F.D.A. must solicit participation for each foreign inspection assignment. However, this creates barriers to timely and effective inspections for regions that are located in difficult-to-reach areas and/or dangerous locales. *See* SUBCOMM. ON OVERSIGHT & INVESTIGATIONS, *supra* note 274, at 4. *See also* Statement of Andrew C. von Eschenbach, *supra* note 281, at 4 (authorization is required from some foreign governments to enter and inspect facilities). This results in the F.D.A. inspecting facilities more conveniently accessed in relatively safe countries, instead of more problematic countries, such as China, which actually has had a decrease in inspections from 2006 to 2007 and ranks eighth, behind India, Germany, Italy, Canada, the U.K., France, and Japan. *See* Letter from Senator Charles Grassley to F.D.A. Comm'r Andrew C. von Eschenbach, M.D. (Feb. 1, 2008), available at http://www.senate.gov/~finance/press/Gpress/2008/prg021208a.pdf (last visited Feb. 15, 2008). Indeed, since 2002, China has had only seventy-five inspections by the FDA. *See id.* at 2. *But see* GOV'T ACCOUNTABILITY OFFICE, *supra* note 34, at 22 (trips are sometimes mandated).

[289] *See* SUBCOMM. ON OVERSIGHT & INVESTIGATIONS, *supra* note 274, at 4; GOV'T ACCOUNTABILITY OFFICE, *supra* note 34, at 22-23.

[290] *See* Press Release, Grassley, *supra* note 273.

[291] According to a former F.D.A. official, in 1998, the F.D.A. had fifteen different data systems to identify foreign pharmaceutical manufacturers, plan foreign inspection travel, track inspection results, and monitor enforcement actions. *See* Statement of Benjamin L. England, *supra* note 262, at 7.

[292] *See* Bridges, *supra* note 275; GOV'T ACCOUNTABILITY OFFICE, *supra* note 34, at 12, 14; *see also* Statement of William K. Hubbard, *supra* note 25, at 7 ("The information technology systems used by F.D.A. to track registrations of foreign drug manufacturers and actual imports from those manufacturers are not linked and are so

in failure of the F.D.A.'s selection process to identify establishments that are of high priority for inspection.[293] Integrating or creating new databases under the bill's proposal of importer and exporter registration into the currently chaotic system will be a tremendous challenge that will either further exacerbate the problem or will take additional significant resources, diverting these away from inspection efforts.

In addition, the dynamics of foreign manufacturer inspections also create oversight issues that would greatly impact inspections contemplated by the bill. Location of these plants in rural areas poses challenges for inspectors.[294] Further, these inspections are often confrontational, with language being a problem for oral communication and documentation review.[295] Further, translators are hired by the inspected facility, causing tremendous conflict of interest issues.[296] The process allows for a foreign manufacturer to be "in almost a totalitarian position to control the inspection from the time an investigator lands to the time of departure."[297] And with the grueling and tight travel schedule for these inspections, inspection quality is compromised since additional days are not available to more deeply assess identified problems the way they are available in domestic inspections.[298] Senior pharmaceutical representatives noted that domestic inspections may be unannounced and often last as long as a week, and even up to a month; meanwhile, a typical foreign inspection that lasts only two to three days, is announced significantly ahead of time, and occurs in a foreign language is unlikely to substantively assess whether the foreign facility adheres to cGMP compared with unannounced, detailed visits that may last weeks.[299]

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poorly coordinated that F.D.A. inspectors often cannot tell if a firm actually importing a drug is even registered at all."). This situation was also extant in earlier hearings occurring in 2000. Statement of Benjamin L. England, *supra* note 262, at 5-7.

[293] *See* GOV'T ACCOUNTABILITY OFFICE, *supra* note 34, at 19.

[294] *See* SUBCOMM. ON OVERSIGHT & INVESTIGATIONS, *supra* note 274, at 2 (reporting that many manufacturers are located in remote, rural areas).

[295] *See id.* at 3.

[296] *See id.*; GOV'T ACCOUNTABILITY OFFICE, *supra* note 34, at 23.

[297] Statement of Carl R. Nielsen, *supra* note 28, at 10.

[298] *See* SUBCOMM. ON OVERSIGHT & INVESTIGATIONS, *supra* note 274, at 3-4.

[299] *See id.* at 4 n.6. As noted by a former FDA official,

> a rare 2-3 day foreign inspection by itself will not adequately assess compliance with cGMP requirements. . . . Generally, the domestic industry is subject to unannounced inspections under FDA's statutory authority. Meanwhile, the foreign industry receives several weeks' advance notice of FDA's intent to inspect. This interlude provides foreign industry an opportunity to prepare

As might be expected from its problems with parallel trade,[300] the European Union is no better. Similar to the United States, roughly eighty percent of the volume of active pharmaceutical ingredients used in E.U. medicines comes from abroad (much of it from Asia), compared to almost none twenty years ago.[301] E.U. authorities cannot determine specifically how many factories actually supply active pharmaceutical ingredients for medicines imported there.[302] Compared with domestic E.U. manufacturers, enforcement of cGMP requirements on foreign entities is often limited, resulting in only "'voluntary' regard for expensive cGMP" by these firms.[303] E.U. oversight, inspection, and law enforcement, with respect to foreign drugs and their manufacture, is lacking, "especially involving importation of [active pharmaceutical ingredients] into the [E.U.] . . . [and represents an] opportunity to import sub-standard (counterfeit) [active pharmaceutical ingredients] with a low chance of being caught."[304] Indeed, one commenter from Europe indicates that the issue is even more serious than simple "mere" non-compliance with cGMP: "[i]t appears that even companies in China and India that have been blacklisted by Nigeria's health authority . . . because of their proven, deep involvement in exporting counterfeit medicines to that country[] are still freely exporting [active pharmaceutical ingredients] to the [E.U.]"[305]

Hence, with its current constraints, the primary safety agency for medications in the United States is "understandably in a difficult position"[306] in its bid to maintain the security of the domestic drug

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> and put on the best face for the FDA inspector knowing the inspection will likely be of a specific duration and knowing the likelihood of a timely re-inspection is remote.

Statement of Carl R. Nielsen, *supra* note 28, at 8, 10; *see also* Statement of John B. Dubeck, *supra* note 273, at 2 (observing that domestic inspections are unannounced, may extend over many weeks, may involve several separate visits of one or more days, while foreign facilities are not subject to such requirements).

[300] *See supra* notes 144-154 and accompanying text (discussing weaknesses associated with parallel trade).

[301] Statement of Guido Villax, *supra* note 273, at 1.

[302] *Id.* at 5.

[303] *Id.* at 2.

[304] *Id.* at 3.

[305] *Id.* at 5.

[306] *See* Press Release, Grassley, *supra* note 273. Note that the same challenges of pharmaceuticals that plague the F.D.A. also apply to F.D.A. medical device oversight—limited inspections (but worse; even domestic firms are not inspected as often as they should be), as well as poor database tracking and coordination of foreign medical device manufacturers—make safety in this arena limited as well. *See, e.g.*, Sam Baker, *GAO Tells Lawmakers Foreign Device Makers May Go Decades Without F.D.A. Inspections*, INSIDE HEALTH POLICY, Feb. 1, 2008,

supply. Challenges in the European Union, weaknesses in intercepting poor quality, counterfeit drugs within the U.S. borders, and the stark inability to ensure the safety and effectiveness of products made outside the United States, combine to create a highly vulnerable system. As noted by a veteran F.D.A. official, "the current paradigm is grossly inadequate, is held together by bailing wire, and is incapable of determining or verifying the safety and efficacy of most imported drug products."[307] Hence, importation proposals that focus on the price aspect of access, even assuming some price reductions that in fact may not materialize,[308] completely ignore the tremendous safety issues that are the current reality for foreign drugs and place the risks of policy failure on the most vulnerable.[309]

V. A POLICY PROPOSAL

A. A Framework for Change

The tremendous problem of access—and its related components of price and authenticity—is of great interest to all stakeholders in the U.S. delivery system. Vulnerable patients without affordable, authentic drugs get sicker and cannot fulfill their economic and social potential. Pharmaceutical companies are cheated out of revenue, which may lead to price increases to cover anti-counterfeiting activities and even less access and more incentives for counterfeiters

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available at http://www.insidehealthpolicy.com (last visited Feb. 4, 2008). However, the medical device oversight by the F.D.A. may be even more worrisome because there already is a third-party program to inspect foreign manufacturers that has not been used, and earlier inspections may be necessary for medical devices because they cannot be effectively inspected at the border since they may have to be taken apart and/or desterilized. *See id.*

[307] Statement of Carl R. Nielsen, *supra* note 28, at 2.

[308] *See supra* note 221 (discussing economic analyses showing limited price benefit of importation).

[309] *See, e.g.*, Rene F. Rodriguez, *Drug Importation and the Hispanic Physician*, 36 CAL. W. INT'L L.J. 117, 124 (2005) (asserting that alternative drug programs that create risks of counterfeits, such as drug importation, create a two-tier system that puts the brunt of policy risk upon the poor). Rodriguez is the President of the Interamerican College of Physicians & Surgeons, which represents physicians that predominantly treat low-income Hispanic patients. Note also that minorities and seniors are the most sensitive to price, and may engage in self-denial of medicines. *See, e.g.*, Geoffrey F. Joyce et al., *Pharmacy Benefit Caps and the Chronically Ill*, 26 HEALTH AFF. 1333, 1342 (2007) (reporting that seniors may quit taking drugs when medication benefits caps are reached); Michael A. Steinman et al., *Self-restriction of Medications Due to Cost in Seniors without Prescription Coverage*, 16 J. GEN. INTERNAL MED. 793, 795-96 (2001) (reporting that seniors and minorities self-limit medication purchases on basis of resources, which may lead to risky purchases and vulnerability to counterfeit drugs).

to enter into the market. The root causes of high prices, low costs, the gray market and parallel trade, the Internet, and limited suspicion by providers and patients have created a sketch of the public health problem, but also a strategy for change.

B. A Policy Proposal: Overview

To address the issue of vulnerable patient access to drugs, on both a price and authenticity level, several aspects of the U.S. system must be addressed. First, a no cost/low cost drug program for these patients should be created by Congress, preferably based upon extant infrastructures, and coordinated by those knowledgeable about the needs of vulnerable patient populations. Second, the issues of gray market and parallel trade should be addressed through a system of identifiable, registered wholesalers as well as the use of guidance to help larger purchasers obtain medicines from legitimate sources. Importantly, importation of drugs meant for foreign markets with their increased risks and burdens on an already overloaded system should be prohibited. Third, in this same light, the problems with Internet purchases of drugs should also be avoided by prohibiting sale of medicines over the Internet except by sellers accredited by independent, rigorous assessments. Fourth, to guard against counterfeits, an aggressive public health campaign should be waged to raise awareness amongst patients and providers regarding risks of counterfeit drugs. Finally, penalties should fit the crime, and criminal penalties should be increased to deter those who prey upon the sick and the vulnerable.

C. A Policy Proposal: Federal Statute

To accomplish the goal of price access, while taking into account the issues that lead to authenticity problems with counterfeit drugs, a statutory means is the most direct and efficient.[310] This strategy is adopted here on the federal level.

[310] *See, e.g.*, Richard A. Epstein, *The Social Consequences of Common Law Rules*, 95 HARV. L. REV. 1717, 1717-19 (1982) (implying that legislation is a more efficient and effective method to achieve social change than common law).

A Bill

H.R. ——

To amend the Public Health Service Act to provide for access to safe, authentic drugs, and for other purposes.

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A BILL

To amend the Food, Drug, and Cosmetic Act to provide for access to safe, authentic drugs, and for other purposes.

Be it enacted by the Senate and the House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Access to Safe, Authentic Drugs Act."

SECTION 2. FINDINGS.

Congress makes the following findings:

(1) Medicines provide significant benefits to citizens of this country.

(2) However, many citizens do not have access to medications.

(3) Because of high prices, many citizens, particularly vulnerable patients such as minorities, seniors, and those lacking insurance, cannot afford medications.

(4) Further, these citizens may attempt to access medicines from suspect sources, such as the Internet, in other countries, and from other risky sellers, leading to purchases of counterfeit drugs.

(5) Patients are harmed and/or killed by counterfeit drugs.

(6) Challenges in the drug distribution system, including the large market of secondary wholesalers, allow for counterfeit drugs to enter into the legitimate supply chain, while parallel trade issuers internationally create similar problems with the international supply chain.

(7) The sale and use of counterfeit drugs violates intellectual property laws and deprives legitimate drug companies of revenue from their investments in product development.

(8) Patients and health care providers have limited knowledge of the risks and presence of counterfeit drugs.

The Preamble and Sections 1 and 2 serve as the foundation for the purpose of the Act. The preamble notes that the Act will amend the Food, Drug, and Cosmetic Act.[311] The key aspects of access—both financial and authenticity components—are noted here relating to vulnerable patient populations in this country. The problems of suspect sources and counterfeit drugs are highlighted. Furthermore, the causes relating to the Internet, gray market domestically, and parallel trade internationally, are also noted in the context of access. Finally, the limited awareness of the problems of counterfeits by patients and providers is also noted.

As indicated previously, vulnerable patients, for example those with fixed incomes and those without health insurance, including many of those in minority groups, are particularly price-sensitive and are highly subject to risks associated with counterfeit drugs.[312] Hence, these patients, who have limited access in both senses of the term, should be provided with such access. Using a low cost/no cost drug program can accomplish these goals by addressing both price and authentic drug access for these groups.

SECTION 3. ACCESS TO SAFE AND AUTHENTIC DRUGS THROUGH NATIONAL LOW COST/NO COST DRUG ACCESS PROGRAM.

(a) IN GENERAL.—Section 515 of the Food, Drug, and Cosmetic Act (21 U.S.C. § 355), is amended by adding at the end the following Subsections:

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[311] 21 U.S.C. §§ 301-399 (2006).

[312] *See supra* notes 112-116 (discussing price-sensitive vulnerable patient populations).

"(O) ACCESS TO DRUGS.—

(1) NATIONAL LOW COST/NO COST DRUG ACCESS PROGRAM.—The Secretary shall direct the Department of Health and Human Services Office of Minority Health to—

(a) identify private and public low and no-cost drug programs in the United States of America, including those with culturally competent and language translation services, and identify all state-level Offices of Minority Health;

(b) develop an integrated, national program, the National Low Cost/No Cost Drug Access Program, to provide access to low and no-cost drugs for minority and vulnerable patient populations under 400% of the federal poverty levels, utilizing and expanding upon programs identified in section (o)(1)(a) above, with the assistance of the Department Advisory Committee on Minority Health, state-level Offices of Minority Health, and industry members and groups, as appropriate;

(c) work with state governments to integrate the national program developed in (o)(1)(b) to also enroll participants into eligible health programs, such as, but not limited to, Medicaid, State Children's Health Insurance Programs, Supplemental Security Income, Medicare Part D, state high-risk insurance programs, and other programs;

(d) provide outreach and access to this national program for minority and vulnerable patient populations; and

(e) develop appropriate education, terms, and conditions of participation to ensure that access to drugs is provided to minority and vulnerable patient populations, and that identification of any adverse reactions or events associated with these drugs are noted, reported, and disseminated."

This National Low Cost/No Cost Drug Access Program ("DAP") has several advantages.[313] First, it would reduce the incentive for patients to purchase from risky sources. By having authentic, legitimate drugs available to them, the program breaks or weakens the chain between the purveyor of counterfeit drugs and vulnerable patients. At the same time, it promotes intellectual property policy by cutting out the producer of fake drugs and maintaining the market use of legitimate, authentic drugs.

Second, a foundation for such a program already exists. The industry's trade group, the Pharmaceutical Researchers and Manufacturers of America, has in fact created the Partnership for Prescription Assistance.[314] This program is a clearinghouse for public and private programs that provide no cost/low cost drugs to those in need.[315] Importantly, this program is culturally sensitive, with access to prescription assistance in multiple languages and the ability for assistance by phone, which is also important for literacy-challenged adults.[316] Developing the DAP, therefore, would not be from the ground up, but would instead build upon an existing, established infrastructure, which should make implementation of a sound program less costly than a *de novo* policy effort.

Third, the proposed program uses extant expertise in the DHHS Office of Minority Health.[317] The Office, as well as its state equivalents, and the Advisory Committee on Minority Health have programmatic knowledge of health care systems and populations that can assist in the creation of the DAP.[318] Using expertise from the

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[313] I have proposed a similar no cost/low cost drug program in a more limited context as part of a proposed statute for regulating biological drugs. *See* Liang, *supra* note 186, at 442-44. This is an economically appropriate approach; *see* Danzon & Towse, *supra* note 102, at 13 ("The ideal solution in such cases is to separate the submarkets within the country, for example, by establishing a program that serves the low-income subgroup only, with discounted prices that are not available to the higher income subgroup.").

[314] *See* Partnership for Prescription Assistance, http://www.pparx.org (last visited Sept. 12, 2007).

[315] Partnership for Prescription Assistance Overview, https://www.pparx.org/about.php (last visited Sept. 12, 2007).

[316] The phone number for the Partnership for Prescription Assistance is 1-800-4PPA-NOW (1-800-477-2669). *See* Partnership for Prescription Assistance, *supra* note 314; *see also* Bryan A. Liang, *Limited English and Health Proficiency: A Call for Action to Promote Patient Safety*, 3(2) J. PATIENT SAFETY 57 (2007) (discussing limited literacy and English proficiency as important issues for consideration in promoting safe drug access).

[317] *See* U.S. Department of Health and Human Services, Office of Minority Health, http://www.omhrc.gov (last visited Sept. 2, 2007).

[318] *See* U.S. Department of Health and Human Services, Advisory Committee on Minority Health, http://www.omhrc.gov/templates/content.aspx?ID=3872 (last visited Sept. 2, 2007).

DHHS Office of Minority Health, Advisory Committee on Minority Health, and state Offices of Minority Health can provide a framework for the conditions and terms necessary to best ensure access to these drugs among specific vulnerable patient populations. These groups will have an understanding of communities, locales, and drug requirements sensitive to each area's unique requirements.[319]

Fourth, an integrated program that not only provides access to drugs, but also to public insurance programs with language assistance, will promote access to health care by overcoming cultural and societal barriers while connecting those eligible for services to the public programs to which they are entitled.[320] This approach can be an important outreach method to increase access, not only to drugs, but also to health insurance and, therefore, health.[321]

Fifth, such a coordinated programmatic effort provides another benefit: important opportunities to monitor relatively unknown drug reactions in vulnerable patient populations. Unfortunately, it is the current scientific reality that clinical trials for drugs in the U.S. that served as a basis for marketing approval have woefully low participation by minority patients and seniors. Hence, primary and side effects on the test patient populations are not indicative of those to be expected for these groups.[322] An organized access program would

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[319] For example, geographic locales will have a different distribution of patients, health care providers who serve them (such as free clinics, federally-qualified community health centers), and community resources, such as charitable organizations.

[320] Unfortunately, many patients are eligible for public health insurance but do not access it. *See, e.g.*, Gregory D. Stevens et al., *Enrolling Vulnerable, Uninsured But Eligible Children in Public Health Insurance: Association with Health Status and Primary Care Access*, 117 PEDIATRICS e751 (2006), *available at* http://www.pediatrics.org/cgi/content/full/117/4/e751 (last visited Sept. 2, 2007) (noting that greater than two-thirds of uninsured children in California are eligible for public health insurance coverage). A program that links drug access with health insurance would have great potential to increase the percentage of insureds.

[321] *See, e.g.*, SARA R. COLLINS ET AL., THE COMMONWEALTH FUND, A ROADMAP TO HEALTH INSURANCE FOR ALL: PRINCIPLES FOR REFORM (2007), http://www.commonwealthfund.org/usr_doc/Collins_roadmaphltinsforall_1066.pdf?section=4039 (finding that access to health insurance is directly related to access to high-quality care).

[322] *See, e.g.*, Dorie Hightower, *Minority Participation in Clinical Trials*, BENCHMARKS, Sept. 6, 2006, *available at* http://www.cancer.gov/newscenter/benchmarks-vol6-issue4 (last visited Aug. 4, 2007) (noting that minorities are particularly underrepresented in cancer clinical trials); GOV'T ACCOUNTABILITY OFFICE, PRESCRIPTION DRUGS: F.D.A. GUIDANCE AND REGULATIONS RELATED TO DATA ON ELDERLY PERSONS IN CLINICAL DRUG TRIALS GAO-07-47R (2007) (noting effects of drugs on seniors are not known because many clinical trials exclude them from participation, and calling for better F.D.A. oversight).

allow any differences between reactions of those in clinical trials and the broader, underrepresented groups to be identified.

Here, participation in the DAP is a condition for F.D.A. review and marketing approval. This participation philosophically can be seen as based upon a social contract, where access to and actual F.D.A. review—a partly or wholly-funded activity of the polity[323]—is part of the consideration of the social bargain for F.D.A. drug assessment and, ultimately, access to the lucrative U.S. market.[324] Older drugs are also folded into the program if they were approved after August 1, 1997, to allow access to useful drugs already approved.

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[323] Brand-name drug companies fund a significant fraction of the costs associated with new chemical or biologic drug application review. *See, e.g.*, Prescription Drug User Fee Rates for Fiscal Year 2007, 71 Fed. Reg. 43,780 (July 26, 2006); Prescription Drug User Fee Amendments of 2002, 21 U.S.C. §§ 356b, 379g-h (2006); *see also* SUSAN THAUL, THE PRESCRIPTION DRUG USER FEE ACT (PDUFA): BACKGROUND AND ISSUES FOR PDUDA IV REAUTHORIZATION 14 (Cong. Research Serv., 2007), *available at* http://opencrs.cdt.org/rpts/RL33914_20070313.pdf (reporting that, in Fiscal Year 2006, user fees covered 19.9% of F.D.A. salary and expenses); F.D.A., FY 2005 PDUFA FINANCIAL REPORT 4 (2006), *available at* http:// www.fda.gov/oc/pdufa/finreport2005/PDUFA05finrpt.pdf (reporting that user fees accounted for 56% of all F.D.A. funds from all sources in support of human drug application review). At the present time, generic drug application review is not funded by generic company applicants.

Yet the polity picks up the rest of the costs. Also, clinical trials require participation by citizens of this country, and research funded by polity resources, such as public grant-funded work and research performed by the National Institutes of Health, the National Science Foundation, and others, benefit pharmaceutical companies. This is, arguably, a part of the obligation we have as a society "to avoid compassion on the cheap … [and making] moral free-riders out of all the rest of us." Maitland, *supra* note 102, at 460 (citation omitted). Hence, an exchange that allows for monopoly pricing via the patent regime, resources for additional innovation, and a focus on legitimate drugs being used by patients in exchange for F.D.A. review, participation in the DAP building on extant industry programs, and increased substantive price and authenticity access by vulnerable patient populations, would be a reasonable exchange. This approach avoids the concept of only allowing patent rights if drugs are priced "responsibly." *See id.* at 463-64.

[324] Indeed, this participation can be considered a bargain since the marginal costs associated with making the next dose of a particular drug is extremely small. *See, e.g.*, ARNOLD KLING, ASYMPTOMATICALLY FREE GOODS (2002), *available at* http://arnoldkling.com/~arnoldsk/aimst5/aimst506. html (noting "[t]he marginal cost of manufacturing prescription drugs is low."); Danzon & Towse, *supra* note 102, at 3 ("Marginal cost [of drug production and sales] includes only the variable cost of producing and selling additional units, which is usually very low." (citation omitted)). Further, many drug companies already have extant, but uncoordinated, access programs for low-income persons, indicating DAP participation would be a relatively low burden. *See* Liang, *supra* note 8, at 316. In addition, since "[t]he government is of course free to insist on any contractual terms it wants … in return for making its research available to the private sector," Maitland, *supra* note 102, at 469, participation in the DAP may simply part of this social contract.

This date is chosen because it represents when the F.D.A. issued draft guidance for direct-to-consumer drug advertising that relaxed previous limits on these activities and which have accounted for increased profits for drug companies.[325]

Note, however, that within the bill there is a grace period of eighteen months to allow companies to set up distribution networks and to begin profit-oriented sales before participation in the DAP for their new drugs. As well, because of the monopolistic effects of new drug approval due to patent protections for approved new drugs, such companies are mandated to participate in the DAP for at least fifteen years,[326] whereas generic and other abbreviated application forms that have a more limited life only require participation in the DAP for ten years.[327] In addition, to temper the effects of folding in older drugs,

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[325] *See* Statement of Rachel E. Behrman, M.D., M.P.H., before the Special Comm. on Aging, U.S. Senate, Sept. 25, 2005, *available at* http://www.fda.gov/ola/2005/idcda0929.html; T.V. Terzian, *Direct-to-Consumer Prescription Drug Advertising*, 25 AM. J.L. & MED. 149 (1999); M.B. Rosenthal et al., *Promotion of Prescription Drugs to Consumers*, 346 NEW ENGL. J. MED. 498 (2002); KAISER FAMILY FOUNDATION, IMPACT OF DIRECT-TO-CONSUMER ADVERTISING ON PRESCRIPTION DRUG SPENDING (2003), http://www.kff.org/rxdrugs/6084-index.cfm.

[326] Maitland argues:

> in due course that the economically disadvantaged are better off when drug prices are set by the market. That is because the rich subsidize the development of medications that, within a relatively short time, become available in perpetuity to the rest of the world at little more than the cost of manufacture. In the United States, drug makers are granted twenty years during which they are free to charge whatever the market will bear. After that their drugs are in the public domain.

Maitland, *supra* note 102, at 458. Assuming the validity of this argument, there is still the question of that period of monopoly prices for those who cannot afford them. The DAP would allow for early access without impinging on market pricing, and would expand availability of drug choice to generics, which are also large companies that profit substantially from U.S. drug sales.

[327] New drug applications, or NDAs, are evaluated under § 505(b)(1)-(2) of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(b)(1)-(2) (2006). Every new chemical drug, such as the familiar prescription pills obtained from a pharmacy, *see* Liang, *supra* note 186, at 366-67, is reviewed under the NDA premarketing process by the F.D.A. and must be approved by the F.D.A. before sale, as described in § 505(b)(1). *See id.* at 384-86. Generic chemical drugs are reviewed using an abbreviated approach under the Abbreviated New Drug Application, or ANDA, process, § 505(j) of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j) (2006). *See* Liang, *supra* note 186, at 386-90. Biologic medicines, such as vaccines, cancer drugs, and other injectibles, which are much larger and complex compared to chemical medicines, *see id.* at 368-69, are regulated as both drugs under § 505(b)(2) of the Food, Drug, and Cosmetic Act, and as biologics under § 351 of the Public Health Service Act, 42 U.S.C. § 262 (2006). Smaller biologics, such as insulin and

both brand-name drugs and generics will be deemed to have begun their participation in the DAP as of the date of F.D.A. marketing approval, limiting the duration of these drugs in the DAP.

Because the patients whom this program would benefit are segregated from the private system, it is economically rational for firms to participate in the DAP.[328] Further, such a pricing system would be more equitable, since it would have less of an impact on price-sensitive consumer consumption given the same relative price changes.[329]

To promote security of the drug supply, there must be an established means for purchasers to know that the sources from which they obtain medicines in large quantities are, in fact, legitimate. Hence, to avoid the problems of the gray market, as well as parallel trade issues of questionable sources, a limited number of manufacturer-identified legitimate wholesalers should be provided to the F.D.A. and listed on the Internet at the F.D.A. website for public use.

"(p) SAFETY OF DRUGS.—

(1) MANUFACTURER CONTRACTING WITH DISTRIBUTORS.—Manufacturers of medicines approved for marketing by the F.D.A. shall contract with no more than ten (10) distributors for each product sold in the United States.

(2) DISTRIBUTOR LISTING BY THE F.D.A.—

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growth hormone, are usually reviewed under a parallel NDA application process delineated by § 505(b)(2), whereas new, larger, and more complex biologics are regulated under the Biological License Application process, or BLA, under § 351, which is similar in scope to the NDA process. *See* Liang, *supra* note 186, at 390-92.

[328] As Danzon & Towse note,

> even though patents may in theory enable a firm to charge a price above marginal cost, this may not be in the firm's self-interest in markets where consumers cannot afford to pay. Thus, a patent-holder may rationally set prices near marginal cost in low-income markets where demand is highly price-elastic, provided that these low prices cannot spill-over to other, potentially higher-priced markets in the same country or other countries.

Danzon & Towse, *supra* note 102, at 4.

[329] This approach is known as Ramsey optimal pricing, which provides for price differentials that allow prices to vary inversely across market segments in relation to their demand elasticities. *See* Danzon & Towse, *id.* §3, at 1. The concept is that "more price-sensitive users should be charged a smaller mark-up over marginal cost than less price sensitive users, because the price-sensitive users would reduce their consumption by proportionately more, if faced with the same prices." *Id.* at 4.

> (a) LIST PROVIDED TO THE F.D.A.—Each manufacturer of medicines approved for marketing by the F.D.A. shall supply on an annual basis, and update when necessary, if such listing changes no more than ten (10) days after such change occurs, a listing of all distributors for each product marketed in the United States to the F.D.A.
>
> (b) F.D.A. WEBSITE PUBLICATION.—The F.D.A. shall publish the listing, by drug, of all manufacturer-identified distributors of each approved drug on its website for public use."

In this fashion, legitimate distributors are easily identified for purchasers downstream from the manufacturer. Closed relationships between these groups allow for an assurance of authentic goods passing between them. As well, such a system of identification and registration creates accountability for those who purchase medications to investigate the source and ensure they are dealing with legitimate sellers, precluding the claims that they believed the sellers were legitimate.[330] Such a system of identification and public registration is necessary because previous efforts at private listing of multiple "authorized distributors of record" failed to ensure that the drug supply would be free from counterfeits.[331] Indeed, similar to the scheme proposed here, to address the problems of counterfeit and diverted drugs in the U.K., drug companies AstraZeneca, Napp Pharmaceuticals, Pfizer, and Sanofi-Aventis have limited distributor contracts. They now have only one to three clearly identified companies with whom they contract to ensure that all product is from

[330] A distributor of fake Lipitor® claimed that it was "as much a victim of the counterfeit scheme as consumers of the drug." *See* Dan Margolies, *Kansas City, Mo., Drug Wholesaler Faces Mounting Legal Problems*, KANSAS CITY STAR, Aug. 1, 2003, *available at* http://www.accessmylibrary.com/premium/0286/ 0286-8894161.html. However, Department of Justice authorities found otherwise. *See* Press Release, U.S. Department of Justice, Pharmaceutical Distributor Pleads Guilty to Selling Counterfeit Drugs (Oct. 18, 2006), *available at* http://www.cybercrime.gov/albersPlea.htm. *See also* Blackwell, *supra* note 160 (reporting on Johnson & Johnson lawsuit against Canadian distributor of fake diabetic test strips, sold to U.S. patients, who also claims that he was a victim of a Chinese businessman posing as a legitimate distributor).

[331] *See, e.g.*, EBAN, *supra* note 86 (describing one case where a large wholesaler purchased fake drugs in the gray market from a private, authorized distributor of record, and ended up supplying fake erythropoietin to a CVS Pharmacy).

an appropriate source.[332] Other drug companies have indicated they are considering a similar move.[333] Industries such as consumer goods sellers (e.g., Wal-Mart) and grocery chains have employed comparable strategies.[334]

Of course, related to problems with the gray market and parallel trade, access to safe, legitimate drugs must also address the dangers of importation and the Internet to stop counterfeits supplied from these questionable sources. Sales through these distribution channels should be prohibited, with the exception of the Internet if accreditation requirements are met.

"(3) PROHIBITION OF DRUG SALES VIA IMPORTATION AND THE INTERNET.—

> (a) All drugs approved by the F.D.A. that receive marketing approval under Section 505(b)(1) of this Act, Section 505(b)(2) of this Act, Section 505(j) of this Act, or under Section 351 of the Public Health Service Act—
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> > (i) shall not be permitted to be imported, except under the provisions of Section 381(d)(1) of this Act; and
> >
> > (ii) shall not be subject to sale through Internet sellers.

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[332] *See* Debbie Andalo, *Wholesale: Ripples Made by Pfizer*, 279 PHARMACEUTICAL J. 259 (2007), *available at* http://www.pjonline.com/Editorial/20070908/articles/p259wholesaleripples.html (last visited Sept. 19, 2007); Sarah Holton, *Global Report: Single-Source Supply*, PHARMACEUTICAL EXECUTIVE, June 1, 2007, *available at* http://www.pharmexec.com/pharmexec/Current+Issue/Global-Report-Single-Source-Supply/ArticleStandard/Article/detail/429154?contextCategoryId=124 (last visited Sept. 19, 2007). Although secondary wholesalers have claimed that such an exclusive network of wholesalers would limit timely supplies to patients, one company, Pfizer, has claimed that 99% of orders have been delivered on time and in full. *See* Abbott, *supra* note 68. Although there are other strategies to address this issue, such as uniform pricing with undisclosed discounts in the international context, *see* Danzon & Towse, *supra* note 102, at 16, an issue may be that for a domestic market, the uniform price signal may be lost, particularly in a proprietary system like the U.S. Instead, by mandating that only identified sources are the legitimate sellers of particular drugs, the signal may be clearer for the potential institutional and individual buyer, at least for the U.S. domestic market.

[333] *See* Andalo, *supra* note 332.

[334] *See id.*

> (b) Notwithstanding the provisions of Subparagraph (3)(a)(ii), sellers who are approved as a Verified Internet Pharmacy Practice Site by the National Association of Boards of Pharmacy are permitted to engage in drug sales through the Internet."

Under this provision, the statute makes clear that importation of drugs marketed in other countries is prohibited. This ensures that the tattered F.D.A. mail, port, and foreign inspection programs do not have their responsibilities even more expanded, creating additional vulnerabilities beyond their current challenges.

Further, Internet sales of drugs are prohibited so that the problems of fakes that have been experienced through these channels can be avoided.[335] Note, however, that the statute would allow domestic Internet sales if pharmacies participate in and are accredited by the Verified Internet Pharmacy Practice Site ("VIPPS") accreditation system of the National Association of Boards of Pharmacy ("NABP"). The VIPPS system is a rigorous evaluation system of domestic pharmacies that use the Internet. Created in 1999 in response to concerns regarding Internet sales of drugs, the VIPPS program requires a pharmacy to comply with:

- licensing and inspection requirements of their home state;
- licensing and inspection requirements of each state to which they dispense pharmaceuticals; and
- NABP VIPPS criteria including patient rights to privacy, authentication and security of prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between patients and pharmacists.[336]

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[335] *See supra* notes 161-176 and accompanying text (discussing problems with Internet sales internationally); *see also* Liang, *supra* note 8, at 285 (discussing problems with detecting whether fake drugs are counterfeit).

[336] *See* National Association of Boards of Pharmacy, Verified Internet Pharmacy Practice Sites (VIPPS), http://www.nabp.net/vipps/intro.asp (last visited Sept. 20, 2007). Note that, although states have attempted to police these Internet drug sellers, *see, e.g., Two Online Pharmacies Get in Trouble with the Law*, DRUG TOPICS, Jan. 21, 2008, http://www.drugtopics.com/drugtopics/article/articleDetail.jsp? id=485808

Importantly, VIPPS accreditation requires that all pharmacies using the Internet for sales verify prescriptions.[337] This is a critical oversight step to ensure that authentic drugs are being provided, as well as a patient safety check to ensure appropriate access to these drugs.[338] Verification of VIPPS accreditation can easily be checked on the NABP website.[339]

Note, however, that awareness is lacking in both patients and providers regarding the risks of counterfeit drugs. Hence, the statute mandates that the Department engages in educational efforts regarding this public health issue through the Centers for Disease Control and Prevention ("C.D.C.").

> "(4) EDUCATIONAL CAMPAIGN.—The Secretary shall direct the Centers for Disease Control and Prevention to:
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> (a) create materials to educate providers and patients on the risks of counterfeit drugs in the drug supply;
>
> (b) develop means by which patients and providers may detect potentially fake drugs; and

(describing shutdown and fine, by New Jersey Attorney General's office, of online pharmaceutical seller and Canadian partner that had dispensed medications ordered by a physician with a revoked license, as well as a fake physician), they are limited to actions only within their own states. Hence, VIPPS provides a means to address these issues on a national basis.

[337] *See* National Association of Boards of Pharmacy, Verified Internet Pharmacy Practice Sites (VIPPS) Licensure and Policy Maintenance, http://www.nabp.net/vipps/consumer/criteria.asp (last visited Sept. 20, 2007).

[338] *See* Bryan A. Liang, *Online Pharmacy Bill: A Good Start But Needs More*, THE HILL, Sept. 14, 2006, *available at* http://hill6.thehill.com/index2.php?option= com_content&do_pdf = 1&id =55106 (discussing the problems of Internet pharmacies that sell fake drugs to those who need them to live, as well as products with active ingredients that result in, for example, deaths of teens who access drugs for recreational use without valid prescriptions).

[339] *See* National Association of Boards of Pharmacy VIPPS Database Search Results, http://www.nabp.net/vipps/consumer/search.asp (last visited Oct. 29, 2007). It is essential, however, that consumer educational efforts accompany the VIPPS accreditation, as rogue Internet sellers fake these logos and put them on their websites. *See* Diane C. Lade, *Dozens of Drug Web Sites Falsely Claiming Certification by Professional Groups*, SOUTH FLORIDA SUN-SENTINEL, Jan. 6, 2008, *available at* http:// www.sun-sentinel.com/business/sfl-flhlpinternet0106sbjan 06, 0,2573470.story (last visited Jan. 8, 2008).

(c) raise public awareness of the public health issue of counterfeit drugs."

Note that there is existing guidance to empower patients to understand the risks of counterfeit drugs. The SAFE DRUG checklist is a consumer-based safety tool that allows for patients to understand and check the legitimacy of their drugs.[340] Such consumer tools could serve as a basis of additional materials and campaigns by the C.D.C. to educate the provider and patient community on the risks of counterfeit drugs. A similar checklist for providers has been developed, including one by the International Council of Nurses on the dangers of counterfeit drugs, as well as the Partnership for Safe Medicines S.A.F.E. Sourcing guide for pharmacists and other bulk purchasers.[341] In addition, for both consumers and patients, an email alert system created by the Partnership for Safe Medicines has been developed to warn patients when government counterfeit drug alerts have been issued.[342] These established products and programs can serve as an effective basis for C.D.C. efforts. Such a campaign is essential because providers and particularly patients are the last barrier to harm. Indeed, the need for education is heightened due to the limits in

[340] *See* Partnership for Safe Medicines, An 8-Step Check List for Medicine Safety, http://safemedicines.org/resources/SAFEDRUG.pdf (last visited Oct. 29, 2007) (providing the **S.A.F.E. D.R.U.G.** checklist, educating consumers about using **S**amples to determine baseline responses and information about drugs; checking the **A**ppearance of a drug each time it is taken; noting the **F**eel and taste of the drug at each administration while recording it in a medication diary; and **E**valuating the drug with respect to feel, taste, and medium-term response; if a problem is suspected, patients should call their **D**octor and have a low threshold for suspicion; patients should **R**eport the drug to the relevant authorities (e.g., F.D.A., law enforcement, manufacturer, local pharmacy where purchased); make the drug **U**navailable 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; and finally, patients should **G**ather details of their experience by collecting all the materials (e.g., packaging, package insert, remaining pills) and provide information to law enforcement, the F.D.A. website, and others to allow thorough investigations to occur so that others will be protected by it).

[341] *See* INT'L COUNCIL OF NURSES, NURSES FOR PATIENT SAFETY: TARGETING COUNTERFEIT AND SUBSTANDARD MEDICINES 19 (2005), *available at* http://www.icn.ch/indkit2005.pdf; Partnership for Safe Medicines, Simple Steps for S.A.F.E. Sourcing, http://www.safemedicines.org/resources/documents/safesourcing.pdf (last visited Oct. 29, 2007).

[342] *See* Partnership for Safe Medicines, SafeMeds Alert System, http://www.safemedicines.org/ north_america/action.php (last visited Oct. 29, 2007).

detection noted previously,[343] as well as because of the limited means by which technology can serve as a barrier to counterfeit drugs.[344]

Finally, penalties must be strengthened to fit the crime and to deter those creatures who would attempt to cheat the sick and vulnerable.

> "(q) PENALTIES FOR COUNTERFEIT DRUG SALES.—Section 303(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 333(a)) is amended by adding at the end the following Paragraph:
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> > '(3) Notwithstanding Paragraph (1) or (2), any person who engages in any conduct described in Section 301(I)(2) knowing that the conduct concerns the rendering of a drug as a counterfeit drug, or who engages in conduct described in Section 301(I)(3) knowing that the conduct will cause a drug to be a counterfeit drug or knowing that a drug held, sold, or dispensed is a counterfeit drug, shall be fined in accordance with Title 18 of the United States Code, or imprisoned not more than twenty (20) years, or both, except that if the use of the counterfeit drug by a consumer is the proximate cause of the death of the consumer, the term of imprisonment shall be any term of years or for life.'"

Here, the statute adopts some language from a pending bill that would penalize counterfeit drug sales.[345] It would correct the limited penalties associated with counterfeit drug sales, and increases them to up to twenty years for purveying counterfeit drugs, or life imprisonment, if it is the proximate cause of death to a consumer.

VI. CONCLUDING REMARKS

Medications can produce enhanced longevity and quality of life. It is a tribute to advances in medical science and the ingenuity of human beings that such potential exists in our society.

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[343] *See supra* notes 182-187 and accompanying text (noting weaknesses in counterfeit drug detection by patients and providers).

[344] *See, e.g.*, Liang, *supra* note 74, at 499-513 (describing technological weaknesses in detecting counterfeit drugs); *supra* notes 203-204 and accompanying text (discussing limitations of pedigree and authentication systems that focus on packaging).

[345] Counterfeit Drug Prevention Act of 2007, H.R. 780, 110th Cong. (2007).

Yet, that ingenuity extends to the less desirable side of creativity—the profiteering by those who would seek to kill and to maim patients through selling and distributing counterfeit drugs. The current system of pricing, sale, distribution, law, medicine, detection, and enforcement creates fertile ground for these entities. The most vulnerable of groups shoulder this risk—the sick, minorities, the elderly, and those without insurance.

As pointed out by Edmund Burke, "[w]hat is the use of discussing a man[] [or woman's] abstract right to . . . medicine? The question is upon the method of procuring, and administering them."[346] The unfortunate reality is that adopting strategies, such as importation, that might lower prices but pay no attention to safety is not a policy panacea for addressing the problem of access to medicines in this country. Being killed, maimed, or untreated is not an appropriate tradeoff for spending less money. Similarly, a focus on technology and authentication to shore up the integrity of the supply chain without attention to the price-prohibitive nature of access that drives the vulnerable to sources not so protected also does nothing to provide the benefits of medicine to those who need them most. The safest and most effective drugs in the world provide no benefit for those who cannot afford them.

Hence, to address these issues, a deeper understanding of the dynamics of safety and availability of medicines is necessary. By focusing upon both the authenticity and price aspects of this issue, substantive means to effectuate appropriate social change are possible.

Understanding the multifactoral risks of the drug distribution system and the economic realities allows for improved policy. Here, by proposing a low cost/no cost drug program built upon existing infrastructures and expertise takes into account the price issues associated with access while employing legitimate, authentic drugs. Further, through distributor registration, prohibition of importation, Internet sales only by domestic accredited pharmacies, educational efforts regarding fake drugs, and increased penalties to fit the crime, counterfeits and counterfeiters would be hit on all fronts, and hopefully driven to conclude that they might be better off in some other market.

Overall, enabling access to medicines for those who need them most is a challenging problem. Still, we must ensure that our efforts do not make that problem worse by ill-fated policies reflecting mere political expediency rather than correcting the root causes of the issue. By addressing safety and price together, we can go a long way toward

[346] *See* 1 EDMUND BURKE, THE WORKS OF EDMUND BURKE 481 (1860).

ensuring that those who need medicines get the real thing at an appropriate price while maintaining continued incentives for innovation.