

# OVER THE VIRTUAL AND GEOGRAPHIC BORDERS: UNDERSTANDING IMPORTATION AND COUNTERFEIT DRUGS

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## ABSTRACT

U.S. citizens depend extensively on medicines for health and quality of life. Yet a major problem attends the drug supply: counterfeit medicines. Although currently the United States has a relatively safe, closed system, it has not been immune to counterfeits, and harm associated with counterfeits has occurred here. Further, because terrorist activities have been connected to counterfeit production, and perverse legal incentives only lightly punish drug counterfeiting, terrorists and drug lords have shifted production to this highly lucrative, but less expensive and lower risk, activity. In addition, through secondary wholesaler and provider purchase and sale of drugs in the “gray market,” U.S. drugs may pass through many hands before finally reaching the consumer. This process has allowed fake drugs to enter the supply chain and harm consumers. Similarly, Internet drug purchases also are a source of counterfeit drug importation that harms unsuspecting patients. Broad scale importation may result in opening the U.S. domestic gray market to scrupulous and unscrupulous suppli-

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ers from all over the world and, as has happened in other countries, may significantly increase the number of fakes introduced into ingested medicines. Public policy should ensure that safe, affordable drugs be the goal, with safety as the emphasis. Consumers should use available tools to protect themselves against harm associated with counterfeit drugs.

## INTRODUCTION

Americans rely extensively upon prescription medications to maintain health and quality of life. According to the National Center for Health Statistics, in 2002 at least 1.3 billion drugs were prescribed to patients in physician offices, 196 million in U.S. emergency departments, and 139 million in outpatient settings.<sup>1</sup> Almost two-thirds of visits to physician offices and hospital outpatient departments had at least one drug associated with the visit, and 7% of visits had five or more drugs.<sup>2</sup> In 2004, over 3.5 billion prescription drugs were dispensed by U.S. pharmacies to patients.<sup>3</sup> Estimates indicate that annual expenditures for prescription drugs in the United States top \$230 billion each year,<sup>4</sup> and there is every indication that these numbers will only increase.

In the United States, prescription drug use is ubiquitous. At least 44% of all citizens report using prescription drugs in the last month, and indeed, 17% reported using at least three or more.<sup>5</sup> Seniors use a large portion of these medicines. Greater than 80% of seniors use at least one drug, 50% report taking at least three prescription drugs, and at least 20% of seniors take at least five prescription medications.<sup>6</sup> Although seniors account for only 13% of the population, as patients they account for more than one-third of all prescriptions, and as payers they account for more than 40% of each dollar spent on drugs each

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1. NATIONAL CENTER FOR HEALTH STATISTICS, THERAPEUTIC DRUG USE, <http://www.cdc.gov/nchs/fastats/drugs.htm> (last visited Aug. 16, 2005).

2. *Id.*

3. IMS HEALTH, U.S. PRESCRIPTION ACTIVITY BY CHANNEL, 2004 (Jan. 2005), [http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_49695974\\_68913551,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695974_68913551,00.html).

4. IMS HEALTH, U.S. PURCHASE ACTIVITY BY CHANNEL, 2004 (Feb. 2005), [http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_49695983\\_69891354,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695983_69891354,00.html).

5. NAT'L CTR. FOR HEALTH STATISTICS, U.S. DEP'T OF HEALTH & HUMAN SERVS., HEALTH: UNITED STATES: 2004, at 50-54 (2004), available at [http://www.cdc.gov/nchs/data/04trend.pdf](http://www.cdc.gov/nchs/data/hus/04trend.pdf).

6. *Id.*

year.<sup>7</sup> It is estimated that seniors alone will spend more than \$70 billion on prescription medicines in 2005.<sup>8</sup>

The advent of prescription medications has become a powerful tool in the medical arsenal against disease and in promotion of health and quality of life. Yet the success of prescription drugs, and their extensive use, has attracted unsavory characters interested in exploiting vulnerable patients and the market for medicines. These creatures introduce and peddle counterfeit drugs through vulnerabilities in the drug distribution system. In the United States, counterfeits are a growing problem, but our domestic, closed system has so far maintained a high level of safety.<sup>9</sup> However, the rest of the world has experienced, and does experience, the problem with fake medicines due to extensive movement of drugs in and out of countries through licit and illicit importation.<sup>10</sup> Hence, without extensive safety measures, allowing large-scale importation of drugs into the United States may import the problems of other countries into this one.

#### THE PROBLEM: COUNTERFEITS

Counterfeit drugs are a worldwide problem. The World Health Organization (WHO) reported that a significant portion of the world's drug supply is counterfeit. The scope of the problem is unknown; however, WHO estimates that up to 60% of drugs in some developing countries are fake, and up to 20% are fake in some developed countries.<sup>11</sup> Overall, approximately 10% of all drugs sold in the world are counterfeit.<sup>12</sup> Through importation and reimportation, fake drugs en-

7. FAMILIES USA, COST OVERDOSE: GROWTH OF DRUG SPENDING FOR THE ELDERLY, 1992-2010, at 2 (2000), available at <http://www.familiesusa.org/site/DocServer/drugod.pdf?docID=726>.

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

9. U.S. DEP'T OF HEALTH & HUMAN SERVS., HHS TASK FORCE ON DRUG IMPORTATION: REPORT ON PRESCRIPTION DRUG IMPORTATION 37-38 (2004), available at <http://www.hhs.gov/importtaskforce/Report1220.pdf> [hereinafter HHS TASK FORCE].

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

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

12. *Id.*

ter into country supplies and end up in drugstores, and, ultimately, in patients who ingest or are injected with them.<sup>13</sup>

Although the United States has not experienced the relative degree of counterfeits that other countries have, it has not been immune. For example, in 2003, 200,000 bottles of Lipitor, a cholesterol drug and one of the world's best selling medicines, were recalled due to the discovery that they were counterfeit.<sup>14</sup> In the summer of 2003, blitz inspections by government officials of foreign drug imports at U.S. international mail facilities found that 88% were unapproved, may have been stored inappropriately, and had safety issues.<sup>15</sup> In 2004, U.S. Food and Drug Administration (FDA) officials discovered Mexican drugs imported by U.S. citizens were fake;<sup>16</sup> and in May 2005, the FDA issued warnings on fake Lipitor, Viagra, and an unapproved osteoporosis drug being imported over the Mexican border by U.S. citizens.<sup>17</sup>

Increasing evidence regarding the problem of counterfeit drugs in this country has been piling up. The U.S. Department of Health and Human Services has investigated the issue and in December 2004 issued its report detailing significant security issues associated with drug importation and counterfeit drugs.<sup>18</sup> Notably, there are only 16.9 full-time FDA employees responsible for covering all international mail facilities in the United States to detect incoming counterfeit drugs—and that is not their only duty.<sup>19</sup> With 10,000,000 packages of imported prescription drug products entering the United States each year, it is highly unlikely that the resources devoted to detecting problematic drugs are anywhere near adequate. As well, a story in *Business Week* in February 2005 noted the tremendous increase and market in counterfeit goods worldwide, including counterfeit medicines.<sup>20</sup> Further, the Pharmaceutical Security Institute, a nonprofit trade asso-

13. See WHO, *Essential Drugs and Medicines Policy* (2005), <http://www.who.int/medicines/organization/qsm/activities/qualityassurance/cft/CounterfeitOverview.htm>.

14. See FDA Kicks Off Crackdown on Rising Rate of Counterfeit Drugs: Recalls of Bottles of Fake Lipitor Highlights Problem Infecting Nation's Medicine Supply, CHARLESTON POST & COURIER, July 17, 2003.

15. HHS TASK FORCE, *supra* note 9, at 13.

16. FDA, FDA WARNS CONSUMERS ABOUT COUNTERFEIT DRUGS PURCHASED IN MEXICO (2004), <http://www.fda.gov/bbs/topics/ANSWERS/2004/ANS01303.html>.

17. FDA, FDA WARNS CONSUMERS ABOUT COUNTERFEIT DRUGS PURCHASED IN MEXICO (2005), <http://www.fda.gov/bbs/topics/ANSWERS/2005/ANS01357.html>.

18. HHS TASK FORCE, *supra* note 9.

19. HHS TASK FORCE, *supra* note 9, at 56 fig. 5.3.

20. See Frederik Balfour, *Fakes!*, BUS. WK., Feb. 7, 2005, at 54, available at [http://businessweek.com/magazine/content/05\\_06/b3919001\\_mz001.htm](http://businessweek.com/magazine/content/05_06/b3919001_mz001.htm).

ciation group, reported in May 2005 that problems in counterfeiting, theft, and drug diversion were greatest in the United States for a second year in a row.<sup>21</sup>

The FDA guesses that approximately 1% or less of drugs in the United States are tainted or counterfeit.<sup>22</sup> Assuming only 0.1% of drugs in the United States are affected, in combination with the WHO estimates, this means that approximately 3,500,000 to 350,000,000 prescriptions may be potentially affected by counterfeit drugs each year.

### *What Kinds?*

When counterfeit drugs first started being detected, most fell into the category of lifestyle drugs, for example, Viagra. In some quarters, there was very little sympathy for these victims because of the “designer” and “lifestyle” nature of these drugs. However, recent discoveries include AIDS/HIV therapy, over-the-counter pain medications, antibiotics, insulin, cholesterol drugs, hormone replacement therapy, flu medications, cancer drugs, anti-arthritis drugs, cardiac drugs, anti-parasitic drugs, antihistamines, and many more.<sup>23</sup> The counterfeit market has matured: it has gone from lifestyle drugs to lifesaving drugs. It is likely that all citizens are potentially affected now.

Harm occurs in three ways. If the fake drug contains the wrong drug, the patient is not treated for the disease he or she has. This can occur when, for example, vials (in some cases purchased on online auction sites like Ebay<sup>24</sup>) are relabeled with a fake label as another, more expensive, antibiotic with different bacterial coverage than the one the physician prescribed. This not only does not help the patient get better, but also contributes to the increase in antibiotic resistance of bacterial pathogens, making infections harder to fight.

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21. Julie Appleby, *Stolen, Counterfeit Drug Problems Rise*, USA TODAY, May 10, 2005, available at [http://www.usatoday.com/news/health/2005-05-10-counterfeit-drugs-usat\\_x.htm](http://www.usatoday.com/news/health/2005-05-10-counterfeit-drugs-usat_x.htm).

22. Rudolf & Bernstein, *supra* note 10.

23. Robert Cockburn et al., *The Global Threat of Counterfeit Drugs: Why Industry and Governments Must Communicate the Dangers*, 2 PLoS MEDICINE 302, 304-06 (2005), available at [http://medicine.plosjournals.org/archive/1549-1676/2/4/pdf/10.1371\\_journal.pmed.0020100-S.pdf](http://medicine.plosjournals.org/archive/1549-1676/2/4/pdf/10.1371_journal.pmed.0020100-S.pdf).

24. LEW KONNIK, PHARMACEUTICAL COUNTERFEITING: PREVENTING THE PERFECT CRIME 2 (2004), [http://www.fffenterprises.com/web\\_files/fff\\_wht\\_ppr\\_111804.pdf](http://www.fffenterprises.com/web_files/fff_wht_ppr_111804.pdf). Note that pharmaceutical manufacturing and labeling equipment is also available on Ebay. See, e.g., GLOBAL OPTIONS INC., AN ANALYSIS OF TERRORIST THREATS TO THE AMERICAN MEDICINE SUPPLY 29-30 (2003), available at <http://www.globaloptions.com/booktext2003.pdf>.

The patient may also get the wrong concentration or dose with a counterfeit. This has occurred with Botox treatments, where a physician was supplied with a research version of Botox, which is much more concentrated than that utilized for anti-wrinkle treatment and not intended for human use. It resulted in respiratory paralysis and near death for several patients, including the physician, who was using it himself.<sup>25</sup> Another example was a cancer patient who needed Erythropoietin, which virtually all patients require after chemotherapy because of the latter's side effect of causing severe anemia. Criminals sold a form of the IV drug diluted with bacterially-contaminated water, which was intended to be injected directly into the patient.<sup>26</sup>

The third common method of harm is when the fake drug has no active ingredients. Patients are once again harmed by not being treated, but also harmed by materials used to make the fake drug. This includes bacteria-laced water as IV antibiotics, toxic yellow road paint with floor wax and boric acid<sup>27</sup> (the latter used commonly to kill cockroaches) as an analgesic, and, horrifyingly, antifreeze used to make counterfeit cough syrup. The latter has been documented as killing over 100 children before it was discovered.<sup>28</sup>

### Why?

The answer is easy: money. WHO and the FDA estimate that worldwide sales of counterfeit drugs represent between \$32 billion and \$35 billion annually;<sup>29</sup> that is \$88 million to \$96 million in sales *each day*. Related to this incredible cash flow, the FDA and international government authorities warn that counterfeit drug sales are linked to funding terrorist activities, including those of Hezbollah and

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25. See, e.g., Press Release, U.S. Dep't of Justice, Professor of Ophthalmology/Director of Oculo-Facial Plastic Surgery at University of Kentucky Charged in Fake Botox Prosecution (Mar. 22, 2005), available at <http://www.usdoj.gov/usao/fls/BakerRobertMD.html>.

26. Catherine Wilson, *Two Florida Men Sentenced for Drug Scam*, AEGIS, Aug. 29, 2003, <http://www.aegis.com/news/ap/2003/AP030846.html>.

27. *Continuing Concerns Over Imported Pharmaceuticals: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 107th Cong. (2001) (prepared witness testimony of James Christian, Vice-President and Head of Corporate Security, Novartis International AG), available at <http://energycommerce.house.gov/107/hearings/06072001Hearing267/Christian404print.htm>.

28. *Fact Sheet No. 275*, *supra* note 11.

29. *Id.*; Robert Cockburn et al., *supra* note 23, at 302.

Al Qaeda.<sup>30</sup> The FDA has also identified the drug supply as a target for terrorists.<sup>31</sup>

It is also easy to produce these drugs. Making illicit drugs such as heroin and cocaine is a very difficult, expensive, and highly risky activity. Counterfeit licit drugs on the other hand, are cheap: nefarious producers need only make drugs that *appear* authentic; they do not have to actually work. And it is financially lucrative: a fake pill may cost less than \$0.01 to make, but can be sold for \$0.30,<sup>32</sup> which is still cheaper than the actual drug. And, production can be done by unskilled workers.

Another interesting reason why criminals are turning to counterfeit production is related to pressure from the United States and domestic country governments with illicit drug production. In Latin American countries where a significant amount of cocaine and heroin production occurs, these governments have cracked down on these activities by passing laws that severely punish drug lords for illicit manufacturing. Hence, such production may result in ten to fifteen years in prison.<sup>33</sup> Yet for production of fake licit drugs, penalties may be only six months in jail, and individuals caught can be out on bail in just a few days.<sup>34</sup> Therefore, in an unintended consequence of appropriate penalties for drug lords caught making illegal drugs, a business reevaluation has shifted production to a much cheaper, less risky, and more lucrative product: counterfeit drugs.

A tremendous part of this problem domestically in this country also results from the "gray market." Traditionally, 90% of prescription drugs move from the manufacturer to large wholesalers, then direct to the pharmacies in the community or other facilities such as hospitals and nursing homes. Three large bulk wholesalers dominate this market. However, up to 10% of drugs pass through the gray mar-

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30. GLOBAL OPTIONS INC., *supra* note 24, at 13-14, 69-70, 159-65.

31. Associated Press, *FDA: Al-Qaida Could Poison Medicines*, MSNBC.COM, Aug. 12, 2004, <http://msnbc.msn.com/id/5682351>; *Fake Drugs Are Real Dangers for U.S. Consumers*, PR NEWSWIRE, Aug. 13, 2004, <http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=109&STORY=/www/story/08-13-2004/0002231340&EDATE=>

32. Kerry Capell & Suzanne Timmons, *What's in that Pill? In Latin America, Fake Drugs Are as Lucrative as Cocaine*, BUS. WK., June 18, 2001, available at [http://www.businessweek.com/magazine/content/01\\_25/b3737153.htm](http://www.businessweek.com/magazine/content/01_25/b3737153.htm).

33. *Id.*

34. *Id.*

ket, represented by thousands of interactions between larger and smaller wholesalers and providers.<sup>35</sup>

Theoretically, bulk wholesalers sell direct to customers like consumer and hospital pharmacies, who then dispense these drugs to patients. However, in reality, the “Big Three” wholesalers sometimes buy back drugs to cover short term shortages, while pharmacies and others sell stock when they need cash flow. Excess supplies with impending expirations are sold, bulk drugs are sold to repackagers to create consumer-level sales products, and arbitrage activities result in prescription medicines passing through many hands before reaching the final seller and the patient. This gray market allows tainted and fake drugs to enter the distribution chain, and ultimately, the patient.<sup>36</sup>

Although counterfeit/gray market problems are not well known here, they are internationally. This is due in part to problems with parallel trade, i.e., international drug importation, in Europe and other countries around the world, where drugs may pass through many different countries and scrupulous and nonscrupulous sellers before ending up in a pharmacy.<sup>37</sup> The problem is similar to issues associated with, for example, buying used cars being sold by rental car companies. You may like and trust the person who is selling you the car, but do you trust that all the renters/users of the car did not abuse it, that the car was appropriately maintained, and that there are no hidden accidents or faults? You may trust the representative who is selling you drugs across the counter, but do you trust all the other persons who have handled the medicine to be trustworthy, to have stored the drugs in appropriate conditions, and to have verified their authenticity? Because importation may extend the gray market outside our closed system to worldwide suppliers, the counterfeits problem the world experiences may become our own.

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35. Laura Willard, *Allocating Responsibility for Counterfeit Prescription Drugs*, 8 J. BIOLAW & BUS. 41 (2005); Bette Hileman, *Counterfeit Drugs*, CHEMICAL & ENGINEERING NEWS, Nov. 10, 2003, at 36; GLOBAL OPTIONS, *supra* note 30, at 21-22.

36. KONTNIK, *supra* note 24, at 5-6. Some entities have indicated they will no longer accept drugs from wholesalers who use middlemen. See Jenn Abelsen, *CVS Takes Step to Keep Fake Drugs Off Shelves; Firm Tightens Criteria for Picking Suppliers*, BOSTON GLOBE, May 25, 2005, available at [http://www.boston.com/business/articles/2005/05/25/cvs\\_takes\\_step\\_to\\_keep\\_fake\\_drugs\\_off\\_shelves](http://www.boston.com/business/articles/2005/05/25/cvs_takes_step_to_keep_fake_drugs_off_shelves).

37. KONTNIK, *supra* note 24, at 4 fig.4; WHO, *supra* note 13. Europe has had similar problems with foodstuffs, which represent very much the same dynamic. For example, both Switzerland and Ireland have reported illegally imported foods that are linked to organized crime and unsafe product conditions. See, e.g., Adam Beaumont, *Illegal Meat Trade Sparks Health Fears*, NZZ ONLINE, May 23, 2005, <http://www.nzz.ch/2005/05/23/eng/article5799697.html>; *Illegal Food Import Seizures Rise*, BBC NEWS, May 25, 2005, available at [http://news.bbc.co.uk/2/hi/uk\\_news/northern\\_ireland/4579099.stm](http://news.bbc.co.uk/2/hi/uk_news/northern_ireland/4579099.stm).



## LAW AND THE INTERNET

Importation of medicines is not legal at the current time.<sup>38</sup> But the counterfeit/gray market concern is, nevertheless, a growing problem. This is because importation is occurring through Internet pharmacy purchases. It is estimated that the United States spends \$1 billion on Internet pharmacy purchases each year, and that number is increasing.<sup>39</sup>

Although Web sites may display Canadian or U.S. flags, they may or may not be located in these countries, and clearly there is a question as to whether drugs that are being sold are actually from these countries. One key legal concern: drug shipments through countries like

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38. According to a letter written by Randall W. Lutter of the FDA, virtually all prescription drugs imported for personal use into the United States . . . violate the [Federal Food, Drug, and Cosmetics Act (FFDCA)] because they are either unapproved new drugs (21 U.S.C. § 355), labeled incorrectly (21 U.S.C. §§ 352, 353), or dispensed without a valid prescription (21 U.S.C. § 353(b)(1)). Importing a drug into the United States that is unapproved and/or does not comply with the labeling requirements in the FFDCA is prohibited under 21 U.S.C. §§ 331(d), and/or (a). *See also* 21 U.S.C. § 381(a). FDA approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, packaging location, container/closure system, and appearance. 21 C.F.R. § 314.50. Generally, drugs sold outside of the United States are not manufactured or packaged by a firm that has FDA approval for that drug. Moreover, even if the manufacturer has FDA approval for a drug, the version produced for foreign markets usually does not meet all of the requirements of the United States approval, and thus is unapproved. 21 U.S.C. § 355. The version also may be misbranded because it may lack certain information that is required under 21 U.S.C. §§ 352 or 353(b) but is not required in the foreign country, or it may be labeled in a language other than English (*see* 21 C.F.R. § 201.15(c)). Second, with respect to “American goods returned,” it is illegal for any person other than the original manufacturer of a drug to import into the United States a prescription drug that was originally manufactured in the United States and sent abroad (21 U.S.C. § 381(d)(1)). This is true even if the drug at issue were to comply in all other respects with the FFDCA. Importing a drug into the United States in violation of section 381(d)(1) is prohibited under 21 U.S.C. § 331(t). Thus, to ensure compliance with the FFDCA, any person that intends to import prescription drugs into the United States must ensure, among other things, that it only imports FDA-approved drugs that comply with their FDA approvals in all respects, including manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. 21 C.F.R. § 314.50. The importer must also ensure that each drug meets all applicable U.S. labeling requirements, and that such drugs are not imported in violation of the “American goods returned” provision in 21 U.S.C. § 381(d)(1).

Letter from Randall W. Lutter, Ph.D., Assoc. Comm’r for Policy and Planning, FDA, to Kenny Guinn, Governor of Nevada (May 20, 2005), available at <http://www.fda.gov/oc/opacom/hottopics/importdrugs/guinn052005.html>.

39. Julie Appleby, *Canada’s Cheap Drugs Not the Answer*, USA TODAY, Aug. 28, 2003, available at [http://www.usatoday.com/tech/news/2003-08-27-canadadrugs\\_x.htm](http://www.usatoday.com/tech/news/2003-08-27-canadadrugs_x.htm).

Canada and western Europe are *not* subject to those countries' health safety laws if the products are not earmarked for domestic consumption.<sup>40</sup> Therefore, drugs from India and China, for example, if only passing through Canada en route to U.S. citizens, are not subject to Health Canada safety rules. This legal reality puts in stark relief how international counterfeit/gray market implications can arrive in our very mailboxes and homes.

In addition, the law has had tremendous difficulties in protecting consumers from counterfeits. Consumers cheated and harmed by rogue Internet pharmacies that sell tainted drugs have little recourse against these offshore facilities, which may simply sprout again in another form, even assuming the site is closed. As well, penalties in the United States are weak: for example, counterfeiting a trademark may get the perpetrator ten years in jail, but counterfeiting a drug subjects him or her to only up to three years in prison.<sup>41</sup> Such perverse incentives are akin to the effects of Latin American legal systems that only lightly punish counterfeit drug production.

#### REFORM

Drugs must be authentic and safe to provide the benefits of improved life. But counterfeits are cheating patients of that benefit and possibly exposing them to harmful agents. Weaknesses of the drug distribution and legal systems should be addressed to protect patients from harm. Internet pharmacies and importation efforts should be closely scrutinized to ensure we err on the side of safety to limit the international gray markets and unscrupulous individuals preying on the ill. It bears emphasizing that we need safe, affordable drugs, and safety must come first. Penalties for producing and selling counterfeit drugs should be made at least as severe as producing and selling cocaine and heroin. Law enforcement, providers, and public health and safety agencies internationally should cooperate and establish operations and reporting infrastructures focusing on this huge international industry and problem. Furthermore, technological standardization and

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40. See, e.g., WHO, *supra* note 13; Christine Clark, *British Pharmaceutical Conference 2003: Counterfeiting*, 271 PHARMACEUTICAL J. 453, 454 (2003). "The Government of Canada has never stated that it would be responsible for the safety and quality of prescription drugs exported from Canada into the United States, or any other country for that matter." Diane Gorman, Health Canada Assistant Deputy Minister, Letter to the Editor, WASH. POST, May 9, 2003.

41. FDA, *Protecting Consumers from Counterfeit Drugs*, FDA CONSUMER, May-June 2004, available at [http://www.fda.gov/fdac/features/2004/304\\_drug.html](http://www.fda.gov/fdac/features/2004/304_drug.html).

implementation of methods such as radio frequency ID tags, holograms, and other methods should be supported to stay ahead of counterfeiters to ensure appropriate pedigree and identification of valid drugs.

Patients should also realize that they are the last barrier to harm from these fakes. Using the safety checklist **SAFE DRUG**,<sup>42</sup> available at the Partnership for Safe Medicines Web site,<sup>43</sup> can reduce the chances of harm from counterfeit medications. It focuses upon using **S**amples to determine baseline responses and information about drugs, checking **A**pppearance of the drug each time it is taken, noting the **F**eel and taste of the drug at each administration while recording it down in a medication diary, and **E**valuating the drug with respect to feel, taste, and medium term response. If a problem is suspected, call your **D**octor—have a low threshold of suspicion, and use this article as an excuse if you need one! Then **R**eport the drug to the relevant authorities (e.g., the FDA, law enforcement, manufacturer, local pharmacy where purchased). Make the drug **U**navailable by taking it out of your medicine cabinet, taping the top shut, and marking it with an X in red so it will not be confused with legitimate drugs. Finally, **G**ive details of your experience by collecting all the materials (e.g., packaging, package insert, remaining pills) and outlining your experience to law enforcement and others to allow thorough investigations to occur, so that others will be protected by it.

### CONCLUSION

In the medical world, there is a standard saying on the wards: the chances may be one in a thousand, but when it happens to you, it's 100%. There is no greater place this applies than in the venue of prescription drugs. No financial or legal remedy will replace the life lost or the physical and emotional suffering experienced because of a fake drug. This reality must be remembered when designing our legal systems and processes to thwart those who would prey upon the innocent, vulnerable patient.

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42. The full **SAFE DRUG** safety checklist is included in the Appendix. Such a checklist may become more of the consumer culture. See, e.g., Don Oldenburg, *Consummate Consumer: Raising the Alarm on Rise in Counterfeit Drugs*, WASH. POST, Apr. 5, 2005, at C9 (discussing the **SAFE DRUG** checklist in the context of counterfeit drug information).

43. Partnership for Safe Medicines, *An 8-Step Check List for Medicine Safety*, <http://www..safemedicines.org/resources/safedrug.pdf> (last visited Aug. 16, 2005).

## Appendix

### An 8-Step Check List for Medicine Safety

The Partnership for SAFE MEDICINES

SAFE MEDICINES.ORG

#### S.A.F.E. D.R.U.G.

is a "how-to" guide to help consumers identify and protect against counterfeit medicines. This eight-step check list helps consumers judge whether their medications are safe and provides tips on what to do if a drug has been compromised.



The Partnership for Safe Medicines is committed to helping consumers assure that the prescription drugs they are taking are safe and effective.

The S.A.F.E. D.R.U.G. guide was originally developed by Bryan A. Liang, MD, PhD, JD of the Institute of Health Law Studies, California Western School of Law and the San Diego Center for Patient Safety, UCSD School of Medicine, and refined with the Partnership for Safe Medicines.

**Sample:** Request samples of your medications from your physician when first having a medication prescribed in order to compare the appearance, taste, texture, and reaction later to medications filled through the doctor's prescription. Manufacturer samples are usually only available for brand name medications and not generics. When available, samples will help patients establish a "baseline" of product characteristics. Save the sample's packaging for future comparison. If using the Internet to purchase drugs, make sure the Web site is a "VIPPS" certified site. For a listing of approved sites, see: [www.nabp.net/vipps/consumer/listall.asp](http://www.nabp.net/vipps/consumer/listall.asp). Please note that generics may differ in shape or color and still be a safe and effective product. For specific questions on identification of medications, talk to your pharmacist.

**Appearance:** Compare the prescription medicine you receive with what it is supposed to look like by taking pictures of the original manufacturer's drug and all associated packaging. You can also find pictures in the Physicians Desk Reference available at your local library. When comparing packaging, look for differences in paper, printing (is it the same size, raised print, embossed, etc.), color, and fonts.

**Feel:** Take note of the prescription drug's taste and any associated feeling once you take it. For example, if injecting a medication, is it supposed to burn? Is there anything unusual in your body's reaction compared to previous experiences?

**Evaluate:** How is your body reacting over the course of treatment? Do you feel that you are benefiting from the medication? Is your condition improving, stabilizing, or reverting back to ill health? Ask your doctor or pharmacist what you should expect to feel and when you should expect to begin feeling relief or improvement. Remember: counterfeit drugs can contain no active ingredient, not enough, or too much.

**Doctor:** If your drugs do not seem to have the same taste or if you feel different than usual, immediately write down your symptoms and contact your doctor and pharmacist.

**Report:** If you have any concerns about your drugs, or have confirmed there is a difference in packaging, labeling, or pills, you should immediately contact the pharmacy where you purchased them. You may also want to contact the FDA and the manufacturer of the medication to report your concerns. The FDA can be contacted by calling toll-free 1-800-FDA-1088 (800-332-1088), or on the Web at [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

**Unavailable:** If you confirm that your medicine has been compromised, immediately remove it from your medicine cabinet, mark the packaging with a red pen, and put tape around the top of the drug container so that it will be unavailable to you or others in your family. It is important that you and any family members do not confuse this medication with any legitimate prescription drugs you may be taking. Take the medications to your local law enforcement officials or contact the FDA for more information.

**Gather:** Gather all the information you can find related to how you got the counterfeit medication and how long you have been taking it. One of the key issues is where you purchased the medication. Was it from the Internet, from a mail order, or from a local pharmacy? When did you purchase the medication? Do you still have the packaging? How long have you been taking the counterfeit drugs? If the medication must be taken routinely, you should also contact your physician or pharmacist to arrange for a new supply so that you can resume taking your medication.