

Is the Drugstore Safe? Counterfeit Diabetes Products on the Shelves

May M. Cheng, B.A., L.L.B.

Abstract

It is no longer possible to identify counterfeit medical products, including medications and devices, by simply checking packaging and labeling. Improvements in technology have made it cheaper and easier to produce fake packaging and labels, making it nearly impossible for consumers and authorities to detect counterfeits without conducting tests on the products themselves, as illustrated by the sale of over one million counterfeit blood glucose test strips sold to unsuspecting U.S. consumers at drugstores in more than 35 states and in other countries around the world in the fall of 2006. The pricier the drugs, the more counterfeiters seek to mimic them to maximize returns, victimizing those patients at highest risk who rely on life-saving medications. The interconnected global economy and advances in technology that benefit legitimate businesses and consumers is also benefiting counterfeiters. As pharmaceutical and medical device companies use new technologies and work with governments and international agencies to combat counterfeiting on a global scale, a public awareness campaign is needed to educate consumers to protect themselves.

J Diabetes Sci Technol 2009;3(6):1516-1520

The Growing Problem of Counterfeit Medicines

The problem of counterfeit medicines was first brought to the foreground at a World Health Organization (WHO) Conference of Experts on Rational Drug Use in Nairobi, Kenya, in 1985.¹ Since that time, the proliferation of counterfeit drugs has spread like a cancer, with a jump of 800% between 2000 and 2006.² In 2001 alone, Chinese authorities investigated 480,000 incidents involving counterfeit drugs and attributed 192,000 deaths of patients to counterfeit drug use.³ The WHO currently estimates that as much as 10% of the medication sold globally is

counterfeit.⁴ These counterfeits include brand name and generic varieties of pharmaceutical drugs that are deliberately and fraudulently mislabeled as to the identity or source. In addition, the medicinal ingredients may be in insufficient quantities to provide proper treatment or may simply be replaced with chalk, metal contaminants, or other toxic ingredients.

The explosion of counterfeit products, facilitated by Internet commerce, is not limited to pharmaceutical products.

Author Affiliation: Fasken, Martineau, DuMoulin, LLP, Toronto, Ontario, Canada

Abbreviations: (FDA) Food and Drug Administration, (IMPACT) International Medicinal Products Anticounterfeiting Taskforce, (NAFDAC) Nigerian National Agency for Food and Drug Administration and Control, (RFID) Radio Frequency Identification, (WHO) World Health Organization

Keywords: anticounterfeiting, counterfeit drugs, fake pharmaceuticals, Internet pharmacies

Corresponding Author: May M. Cheng, B.A., L.L.B., Partner, Fasken, Martineau, DuMoulin, LLP, Suite 4200, 66 Wellington St. W., Toronto Dominion Bank Tower, Box 20, TD Centre, Toronto, ON, M5K 1N6; email address mcheng@fasken.com

However, fake medical products have unprecedented health and safety implications, and the proliferation of counterfeit drugs is reaching staggering levels. The trade in counterfeit drugs is expected to grow by an average of 13% annually through 2010, generating \$75 billion in revenue and representing 15% of the size of the legitimate pharmaceutical industry.⁵ Lost profits to the pharmaceutical industry are not the only casualty; the death toll among unsuspecting consumers is growing. In developing countries, the risk is far greater due to the higher prevalence of counterfeit pharmaceuticals (estimated at over 60% in some countries, particularly countries in Southeast Asia and Africa⁵) combined with the fact that most counterfeited medicines are those used to treat infectious and serious diseases, such as malaria, tuberculosis, and HIV/AIDS. However, North American consumers are increasingly at risk due to the proliferation of Internet pharmacies and counterfeit medicine's infiltration of legitimate pharmacies via the supply chain.

The Lure of Internet Pharmacies

There is a market of 47 million Americans with no health insurance or limited drug coverage looking to save money on prescription drugs, and Consumer Reports has advocated the use of Canadian online pharmacies to save 25% on drug costs.⁶ Despite the fact that importation of medicine is illegal in the United States, it is estimated that its citizens are spending \$1 billion on Internet pharmacy purchases each year, and this number is increasing.⁷ This is putting unsuspecting U.S. consumers at very significant risk for purchasing counterfeit drugs.

Law enforcement officials in Canada and the United States have observed that many of these illegal Internet pharmacies deliberately mimic licensed Canadian pharmacy Web sites due to the demand from U.S. consumers seeking to purchase cheaper Canadian pharmaceuticals.⁸ Recent tests conducted by the U.S. Food and Drug Administration (FDA) and U.S. Customs on intercepted shipments of pharmaceuticals to U.S. residents found that 88% of imported pharmaceuticals were counterfeit and contained ingredients that could be harmful.⁹

The inability to take action against Internet sellers of counterfeit medicine is also apparent from the fact that the FDA's Office of Criminal Investigations maintains a list of 24 active Web sites that have been linked to the sale of counterfeit drugs, which appear on www.pharmacycall365.com.¹⁰

Threats to the Health and Safety of Diabetes Patients

Deaths caused by counterfeit medication often do not make the news in developing countries due to how commonplace such occurrences have become. Back in 1988, Dr. Dora Nkem Akunyili, a distinguished professor of pharmacology in Nigeria, witnessed the death of her 21-year-old sister due to hyperglycemia. However, it was not diabetes that killed her; it was the fake insulin supplied to her for treatment.¹¹ A survey published in 2001 by the Nigerian Institute of Pharmaceutical Research indicated that some 80% of the drugs distributed in major pharmacies in Lagos, Nigeria, were counterfeit. Upon her appointment as head of the Nigerian National Agency for Food and Drug Administration and Control (NAFDAC) that same year, Dr. Akunyili became a crusader against counterfeit medicines, getting the police to raid premises, publicly burning mountains of fake drugs and putting suppliers behind bars. Her actions drew the wrath of the fake drug barons who firebombed NAFDAC's offices, and in a December 2003 ambush, six gunmen opened fire on her car. Undeterred, she has continued with a strong grassroots campaign that starts with educating consumers and involving all stakeholders, yielding impressive results. In 2006, the NAFDAC published a new survey showing a 90% decrease in the incidence of counterfeit drugs in circulation and a take of \$100 million in counterfeit drugs seized and destroyed over a 5-year period.¹¹

In February of 2009, it was reported that police in China had arrested four suspects on charges of selling fake diabetes drugs that killed two patients in the remote Northwest region of Xinjiang. The fatal drugs were falsely labeled with a known local brand name and contained illegal quantities of the chemical ingredient glibenclamide, which, while used in the treatment of diabetes, in excessive quantities can cause serious low blood glucose and consequent brain damage.¹²

Examples from developing countries are too numerous to recount. However, increasingly, the sale of counterfeit medical products in pharmacies is no longer isolated to developing countries. In recent years, there have been a number of incidents involving counterfeit blood glucose test strips for use with glucose meters being sold in licensed pharmacies in the United States.

There are over 10 million Americans who measure blood glucose, many of whom rely on at-home diabetes

tests to take sensitive measurements of blood sugar levels to monitor insulin requirements. OneTouch® Test Strips, manufactured by LifeScan, a Johnson & Johnson company, the world's largest consumer-health products maker, were the most successful of these products in the United States. In 2006, about one million phony OneTouch test strips turned up in at least 35 states and in a number of countries in Europe, the Middle East, and Asia. These counterfeit test strip kits, manufactured in China, were found to give incorrect readings, with the potential to cause patients to inject dangerous levels of insulin.¹³ The counterfeiters had accurately copied many elements of the test strip packaging, with the important exception of the lot number on the carton, which was incorrect, enabling the company to identify the fakes and issue public warnings.¹³ The Chinese businessman responsible for their distribution was apprehended and convicted in a Shanghai court in August 2007 and sentenced to 3.5 years in prison, among other penalties.^{14,15}

Also in 2006, Johnson & Johnson and Lifescan successfully brought civil actions in a number of countries arising from these events [for example, *Johnson & Johnson et al. v. Butt et al.* (2007) 162 A.C.W.S. (3d) 232 (Ont. S.C.) and *Johnson & Johnson et al. v. Alexander Vega et al.* (2006) QCCS 5883 (Que. S.C.)]. The counterfeit test strips were sold via two Canadian companies to a number of U.S. distributors, which in turn ended up in over 700 U.S. pharmacies.¹⁶ The case underscores the burgeoning number of fake medical products entering the North American market and the danger of their infiltrating the legitimate supply chain through "gray market" channels that may act as a cover for dealing in illicit counterfeits.¹⁶

In another case involving defective blood glucose test strips in the United States, criminal charges led to a guilty plea in January 2009 by the president of a recycling company in Knox, Indiana.¹⁷ Bayer had discovered that Nor Am Plastics Recycling Inc. fraudulently sold previously recalled test strips on eBay for \$3700 in profits, while Bayer was paying \$8000 to recycle the diabetic glucose strips that were recalled by Bayer.¹⁷ Officials confirmed that over 100 people had purchased the bogus strips, but there were no reports of injuries.¹⁷

International Efforts to Address Counterfeit Drugs

Fueling the counterfeit drug trade are organized crime and terrorist groups from all corners of the world that have seized on counterfeit goods trafficking as a lucrative and low-risk source of funds.¹⁸ The greatest challenge

for anticounterfeiting enforcement is in pursuing counterfeiters responsible for selling fake pills and medical devices via illegal Internet pharmacies or the legitimate distribution chain, as many of these operate outside of jurisdictional borders, creating even greater obstacles to successful anticounterfeiting enforcement. For this reason, international cooperation and coordination is essential to creating solutions for the global counterfeit pharmaceutical products problem.

The WHO has led the effort to combat counterfeit medicines by creating a global partnership called International Medicinal Products Anticounterfeiting Taskforce (IMPACT), composed of all 193 WHO member states and other interested agencies. The purpose of IMPACT is to develop model legislation for effective criminal prosecution, to coordinate efforts to track counterfeit medicines by working with the World Customs Agency, Interpol, and to improve international collaboration of investigation and enforcement across borders.⁴

Other global initiatives are being led by the International Chamber of Commerce, whose Commercial Crime Services Division launched a Counterfeit Pharmaceuticals Initiative in 2003. Counterfeit Pharmaceuticals Initiative was created specifically to tackle the problem of fake pharmaceuticals being sold through illegal Internet pharmacies by collecting and disseminating information on counterfeit pharmaceuticals on a confidential basis with pharmaceutical manufacturers, law enforcement, regulators, and customs worldwide; developing a list of contact points in customs, law enforcement, and regulators who can assist; and opening channels of communication between these agencies across borders.¹⁹

The U.S. Congress has taken aim at illegal activity on the Internet by introducing new legislation called the Fraudulent Online Identity Sanctions Act, which will increase prison sentences by up to seven years for providing false WHOIS information to register a domain name.²⁰

Pharmaceutical companies are also joining the fight against counterfeiters with technologies such as the Radio Frequency Identification (RFID) test program that has been adopted for commonly counterfeited drugs like Viagra, OxyContin, and the AIDS drug Trizivir.²¹ Even the cholesterol-reducing drug Lipitor has been a target due to its popularity as the most widely prescribed drug in the world in 2003, with over 69 million prescriptions written that year in the United States alone.²¹ The U.S. Congress also passed a bill requiring all

prescription drug packaging to incorporate RFID by 2010. Still, no matter how widely adopted, many experts agree that RFID will not stop counterfeiting, because the savvy counterfeiters will simply use legitimate packaging with fake pills or find a way to counterfeit or bypass the RFID bar code.²¹

In addition to RFID validation, Bristol-Myers Squibb introduced "DNA codes" to their anticancer drugs to help combat counterfeiting of their products in 2003.⁵ The DNA codes are 20 or more units long and act as a genetic fingerprint with more than a billion different combinations, which can be read using a small handheld device. More recently, immunochemists have devised a range of nanoscale materials that can be embedded in drug packaging or in the pills themselves to assist with identification of authentic medications by the end user.²² Using traces of FDA-approved ingredients, which are odorless, colorless, and tasteless, detection could be in the form of a field test similar to a pregnancy test. On the packaging for drugs and devices, spectral properties are detectable with light of a specific wavelength.²² Similar technologies are already in use by companies with problems of counterfeit ink cartridges, as the counterfeits have become discernable only by experts using specialized equipment (EPSON, for example, is using this technology for identifying counterfeit ink cartridges).

The FDA has announced a number of initiatives to help combat the growing problem of illegal Internet pharmacies and counterfeit drugs. These include measures designed to support the implementation of an electronic pedigree system and RFID, DNA, and other technologies for all medical products entering the U.S. market to protect the integrity of the supply chain and closer links and cooperation with supply chain members to implement other mechanisms to protect patients.²³

Conclusion

The growing problem of counterfeit medical products in North America will continue unabated unless aggressive steps are taken. The first and most important step is to mount a public education campaign so that American consumers can be made aware of the prevalence of counterfeit medicines and devices, the real threat to their lives and health, as well as learn how to identify the hallmarks of counterfeit products and aid in their detection. Most counterfeit purchases are made by willing consumers, and therefore, the primary focus of changing consumer behavior should start with raising

awareness of risk.³ A heightened awareness of the risk associated with Internet purchases of medications and devices would do much to curb online demand for products where the risk of purchasing counterfeit is greatest. Consumer protection groups, pharmaceutical drug and device companies, and government agencies need to make a public education campaign a priority and devote significant resources to sending strong messages to consumers. In many circles, counterfeiting is still viewed as a victimless crime. Public perception must change in order to have a real impact on the demand side of the equation.

While it is encouraging to note all the international efforts being directed at combating the growing counterfeit pharmaceutical products trade, consumers must also recognize that they are the last barrier to harm from counterfeit drugs and devices. With respect to drugs, all patients should use the eight-step safety checklist guidelines called S.A.F.E. D.R.U.G., available at the Partnership for Safe Medicines Web site, to evaluate the appearance, feel, taste, and baseline responses for any medications they ingest; to ensure that the prescription drugs are safe and have not been compromised; and to report any concerns to authorities.²⁴ With respect to medical devices, consumers should only purchase from authorized dealers and be wary of gray market and Internet sources for devices. No consumer of medical products should ever accept damaged or opened packaging and should always check source and expiry information before purchasing. Consumers also need to be informed about where to report irregularities. Finally, if the price is too good to be true, it is probably counterfeit and not worth taking the risk.

References:

1. World Health Organization. Counterfeit medicines. <http://www.who.int/medicines/services/counterfeit/en/>.
2. CBC News. Phoney drugs a growing threat in developing countries: report. <http://www.cbc.ca/health/story/2008/05/09/counterfeit-drugs.html>.
3. Bird RC. Counterfeit drugs: a global consumer perspective. *Wake Forest Intellectual Property Law Journal*. 2007–2008;8(3):387–406.
4. World Health Organization. Fact sheet 275: substandard and counterfeit medicines. [http://www.who.int/mediacentre/factsheets/2003/fs275/en](http://www.who.int/mediacentre/factsheets/fs275/en).
5. Nelson M, Vizurraga M, Chang D. Counterfeit pharmaceuticals: a worldwide problem. *96 Trademark Report* 1068. 2006.
6. Loeb M, MarketWatch. Three prescriptions for lower drug costs. <http://www.marketwatch.com/story/three-prescriptions-for-lower-drug-costs>.

7. Liang BA. Over the virtual and geographic borders: understanding importation and counterfeit drugs. *California Western International Law Journal*. 2005–2006;36(1):7–18.
8. Halser JL. Canadian pharmacies: a prescription for a public health disaster. *DePaul Law Review*. 2004;54(2):543–88.
9. Robert T, About.com. Tested imported pharmaceuticals: 88% counterfeit. http://headaches.about.com/cs/beforeyoubuy/alfda_ctrfeit.htm.
10. ICANN's Whois data accuracy and availability program: description of prior efforts and new compliance initiatives. <http://www.icann.org/en/whois/whois-data-accuracy-program-27apr07.pdf>.
11. WIPO Magazine. Global congress on combating counterfeiting and piracy—the first three years. http://www.wipo.int/portal/en/new/2008/article_0002.html.
12. Mingxin B. China detains four suspects for selling fake diabetes drugs. http://news.xinhuanet.com/english/2009-02/02/content_10748190.htm.
13. Frank AD, Rapaport L, Bloomberg News. Johnson & Johnson tracks down maker of phony diabetes test. <http://counterfeitdrug.wordpress.com/2008/02/15/johnson-johnson-tracks-down-maker-of-phony-diabetes-test/>.
14. Lifescan. Counterfeit OneTouch test strip alert. <http://www.lifescan.com/company/about/press/counterfeit>.
15. CBC News. Recalls and advisories: counterfeit blood glucose test strips found on U.S. market. http://www.cbc.ca/consumer/recalls/2006/10/counterfeit_blood_glucose_test.html.
16. National Post. Firm suing over fake diabetes test strips. National Post, September 17, 2007.
17. Platt S. Knox CEO pleads guilty to fraud, illegally selling diabetic testing strips. <http://www.wndu.com/localnews/headlines/37185719.html>.
18. DuBose MM. Criminal enforcement of intellectual property laws in the twenty-first century. *Columbia Journal of Law and the Arts*. 2006; 29:481.
19. ICC Commercial Crime Services. Counterfeit pharmaceuticals initiative. <http://www.icc-ccs.org/cib/cpi.php>.
20. McCullagh D. Perspective: privacy reduction's next act. http://www.news.com/Privacy-reductions-next-act/2010-1028_3-5155054.html.
21. Lerer L. Bad medicine. *IP Law and Business*. September 2006: 26–30.
22. Sciencedaily LLC. Counterfeit drugs can kill: nanotechnology fingerprints can certify authenticity. http://www.sciencedaily.com/videos/2007/0209-counterfeit_drugs_can_kill.htm.
23. Pharmaceutical Research and Manufacturers of America. Press release: FDA issues recommendations to fight counterfeit drugs. June 9, 2006.
24. Liang BA, The Partnership for Safe Medicines. S.A.F.E. D.R.U.G. <http://www.safemedicines.org/consumer/SAFEDRUG.pdf>.