



MODERATOR'S GUIDE

21ST CENTURY HEALTH CARE TERRORISM: THE PERILS OF INTERNATIONAL DRUG COUNTERFEITING

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A Dangerous and Criminal Industry

The business of creating, distributing and selling counterfeit pharmaceutical products is an unregulated, criminal and growing part of the global economy. There is one major difference between pharmaceutical counterfeiting and other underground industries: lives are at stake.

Imagine living in a world where doctors were afraid to write prescriptions because it was unclear whether or not the pharmacy had “real” pharmaceuticals. This could be the very dangerous future if the counterfeit pharmaceutical industry continues its growth. This report serves as a primer for those interested in the basics of the global business of counterfeit drugs. It looks at the current size of the market, and its growth in the future.

Pharmaceutical Commerce: A Brief History

In the late 19th and early 20th centuries, quick, easy cures were the core of the so-called “patent medicine” industry, with innumerable shysters peddling panaceas. Today's cable TV spots for Viagra are models of restraint compared to the newspaper ads of a hundred years ago for patent medicines promising cures for everything from depression to diarrhea.

Most of the cures were useless. Some were harmless, and others were extremely dangerous. They might provide some temporary relief from pain or restore energy, but the core ingredients that did the job were alcohol, cocaine and opium.

Eventually, the frauds of the patent medicine world were exposed, leading Congress to pass the Pure Food and Drugs Act of 1906. This Act, which the Bureau of Chemistry was charged to administer, prohibited the interstate transport of unlawful food and drugs under penalty of seizure and/or prosecution of the responsible parties. The principal focus of the Act was the labeling of drugs and food packages. For example, drugs, which are strictly defined substances, could not be sold in any other condition unless the specific variations from the applicable standards were plainly stated on the label. The purpose of this was to protect Americans from basic fraud and counterfeit medication.

One of the Key Problems: Importation

These regulatory standards did not change the consumer's appetite for quick and easy “cures.” That weakness is very much in evidence as America wrestles with the chronic issue of prescription drug costs. And the quick, easy cure of choice these days seems to come down to two words: drug imports.

Our appetite for a solution is understandable. Drug costs in America are a high-value bargain compared to the cost of hospitalization that modern drugs avoid. Because of advanced pharmaceuticals, we are living longer and more productive lives.

But individual drug costs are high, especially for seniors living on Social Security and investment income. Since seniors are by far the biggest users of prescription drugs, monthly pharmacy bills of \$300 and \$400 a month are not uncommon.

Many well-intentioned people, some of them public officials, believe that the key to containing drug costs in the United States is to legalize and encourage the widespread importing of drugs from foreign countries where government-imposed price controls allow the sale of drugs at prices lower than those charged for name-brand drugs in a United States pharmacy.

When importing drugs comes into play a health care Pandora's box opens. Like the addictive patent medicines of a hundred years ago, widespread drug imports create more problems than they would solve. That applies in particular for drugs imported from Canada. United States advocates of drug imports like to suggest special importing arrangements with Canada because it is perceived as a de facto peer of the United States. Canada is a stable democracy with a legal system very much like ours, and a national health agency that guards the purity of drugs sold in Canada just as aggressively as the FDA does in the United States.

None of this guarantees the safety of drug exports from Canada to the United States – and nobody is more adamant about that than the Canadians themselves. Health Canada, the country's national health agency, has been up front about saying they cannot possibly monitor drug shipments across the United States border. Some of these drugs are not even produced in Canada.

Through a process known as transshipment, drugs come into Canada from around the world, including developing countries like China, Chile, India, Belize, the Bahamas and Vietnam. Most of these third-country drugs are mailed to customers in the United States from the growing number of Internet pharmacies in Canada that take prescriptions from Americans, sometimes with the help of Canadian physicians hired to co-sign prescriptions.

While Canada's pharmacy standards are close to the United States, there still remains a greater chance for misunderstanding or outright deception when something as important as a personal prescription is handled over the Internet. That danger was underscored in July 2004 when the FDA found that a Canadian website pharmacy advertising Canadian generic drugs was in fact selling fake, contaminated and substandard versions of three widely prescribed medicines.

In the government-controlled health market of Canada, the supply of legitimate drugs sold in each province is sharply rationed. Diverting more and more of this limited supply for sale to Americans is aggravating a shortage of some drugs. In fact, this prompted Health Minister of Canada to recently warn, "Canada cannot be the drugstore of the United States." Canada's government also appears to be looking to shut down transshipment of drugs. This should help weaken counterfeit trade, but certainly will not stop it.

Not only is evidence mounting in Canada and the United States, but also threatening numbers are developing across the world. According to a 1997 report from the World Health Organization (WHO), 10%-20% of drugs tested in developing countries failed the most basic quality test, meaning the medicines are either counterfeit or that they have not been handled according to manufacturer specifications.

In Europe, profiteers masquerading as pharmacists are selling unsafe, unregulated, mislabeled, repacked, and co-mingled drugs to unsuspecting consumers – otherwise known as parallel trade or re-importation. In August 2004, counterfeit medicines were found in the legitimate British supply chain after a patient complained of a crumbling tablet. The U.K.’s Medicines and Healthcare products Regulatory Agency (MHRA) issued an immediate alert. Only days later, the MHRA had to issue *another* alert after a different counterfeit medicine was found in Britain’s legitimate supply chain.

Last year, 140 million individual drug packages were parallel-imported throughout the European Union – and a wholesaler repackaged each and every one. These parallel profiteers are in the moneymaking business, not the safety business. Mistakes happen. For example, new labels incorrectly state the dosage strength; the new label says the box contains tablets, but inside are capsules; the expiration date and batch numbers on the medicine boxes do not match the actual batch and dates of expiration of the medicines inside. Patient information materials are often in the wrong language or are out of date.

Therefore, drugs purchased from a British pharmacy by an unknowing American consumer could come from European Union nations such as Greece, Latvia, Poland, Malta, Cyprus, or Estonia. In fact, parallel traded medicines account for about 20% of all prescriptions filled by British pharmacies.

The Facts and Figures

According to a recent study by the European Federation of Pharmaceutical Industries and Associations, 50% of the entire pharmaceutical sales market in Pakistan is constituted of counterfeit medicines, similar to China and Nigeria. The largest counterfeit market with proximity to the EU free trade zone is Russia, where the generally accepted estimate is that 12% of drugs are counterfeit. Now that the Baltic nations of Latvia, Lithuania, and Estonia have joined the European Union, the WHO has warned that an increase in the risks of counterfeits entering the EU supply chain is “obvious.”

We estimate that globally, counterfeit pharmaceutical commerce will grow to become 16% of the aggregate size of the legitimate industry, a six percentage-point increase from 2004. This illegal business will generate \$75 billion in revenues for its owners in 2010, a 92% increase from 2005.

Global Pharmaceutical Commerce Estimates

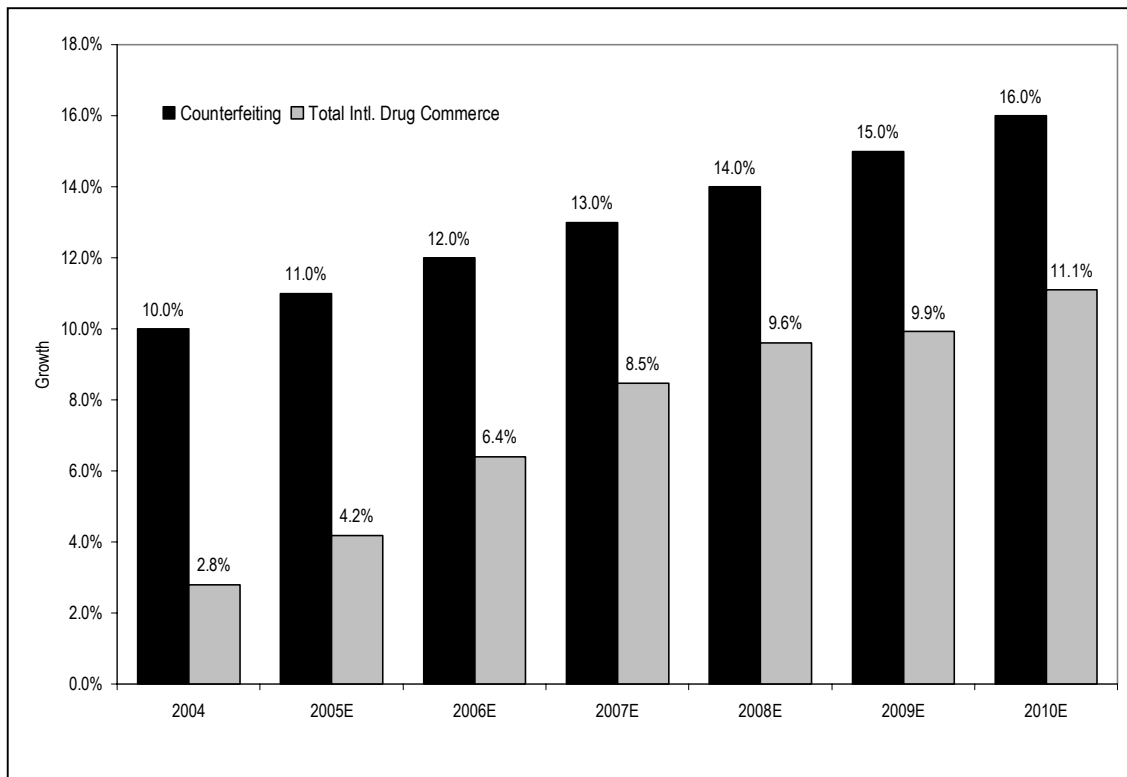
	2004	2005E	2006E	2007E	2008E	2009E	2010E	CAGR
Counterfeiting	\$35.20	\$39.07	\$43.76	\$49.45	\$56.37	\$64.83	\$75.20	13.0%
<i>Growth</i>	<i>10.0%</i>	<i>11.0%</i>	<i>12.0%</i>	<i>13.0%</i>	<i>14.0%</i>	<i>15.0%</i>	<i>16.0%</i>	
Percent of Total	10.7%	11.4%	12.0%	12.5%	13.0%	13.6%	14.2%	
Total Intl. Drug Commerce	\$328.97	\$342.74	\$364.67	\$395.60	\$433.63	\$476.68	\$529.58	7.5%
<i>Growth</i>	<i>2.8%</i>	<i>4.2%</i>	<i>6.4%</i>	<i>8.5%</i>	<i>9.6%</i>	<i>9.9%</i>	<i>11.1%</i>	

Source: Author’s calculations.

The counterfeit industry is also growing at a much faster rate than the legitimate pharmaceutical business. We estimate counterfeit drug sales will grow 13% annually through 2010, compared to just 7.5% estimated annual growth for global pharmaceutical commerce. Many of the products sold via drug traffickers contain ingredients that could

be harmful, and these products are coming from illegal operations with very poor controls.

Counterfeit Drug Growth, 2004 – 2010E



Source: Author's calculations.

Our projections are conservative. We have extrapolated these projections from current industry trends, reports, and earlier reports from the Food and Drug Administration and the WHO's widely quoted facts and figures related to the dangers of counterfeit medicines. The WHO report – now several years old – clearly states that the size of the illegitimate business is nearly 10% of the global market for pharmaceutical trade in industrialized nations, or \$22 billion several years ago. As such, we believe our estimates are *conservative*, as we begin our study with a base figure of 10% of the market. We have merely estimated conservative growth from 2002 to 2004 in the overall pharmaceutical marketplace.

Arrests are Happening...But it is Not Enough

How do we combat this burgeoning illegal industry? Arrest criminals, just like in any other illegal operation. On September 8, 2005, eleven Chinese citizens and an American man were arrested in a counterfeit medicine scheme that spanned 11 countries and involved millions of dollars worth of fake drugs. Chinese police seized 440,000 fake pills in the eastern port city of Tianjin and two cities in central Henan province, and arrested 11 men between August 1 and September 2, 2005.

One American was involved in the illegal trafficking ring. Richard Cowley, a Washington state resident, was charged with importing and distributing counterfeit

goods. The seized drugs, worth \$4.3 million, included the male sexual dysfunction drugs Viagra, Cialis and Levitra.

Authorities believe this particular arrest was one of their most significant investigations involving counterfeit pharmaceuticals. At \$4.3 million, that's just the tip of the iceberg in a multi-billion dollar industry.

As this report was going to print, Ontario authorities were investigating several potential incidences of counterfeit pharmaceutical fraud throughout the province's pharmacies. One former pharmacist in Hamilton, Ontario was charged with five criminal offences when, for the first time, Canadian Mounties found evidence that counterfeit drugs had been legitimately sold through a pharmacy. The local police investigated the deaths of eleven deaths that took place from customers that were taking pharmaceuticals administered there, ruling out just six. At the time of this report printing, the investigation was still underway.

The Solution: Stronger Not Weaker Controls

With the global supply of counterfeit drugs huge and growing, it is obvious that the United States drug market, which accounts for nearly 50% of the world's medicine sales, would be a prime target for counterfeiters, especially if we make their job easier by weakening our current drug import protections. The even greater fear is that massive drug imports would create a major opportunity for international terrorists to kill thousands of Americans with intentionally contaminated drugs packaged as legitimate pharmaceuticals.

These are the risks we face in our daily lives in the 21st Century of health care. For the better part of the last hundred years, Americans have gone to their pharmacy purchase prescription drugs with total confidence that the medicine in the container is precisely what the doctor ordered. That comfort level is something we have taken for granted. We must act immediately to maintain this standard in the health care industry – just as we have increased security measures in aviation. With serious and timely attention to this threat, we can retain that which we hold so dearly – access to high quality health care and life saving drugs.

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