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## The 'global disaster' of fake internet pharmacies

By Katrina Megget

**It might not be Armageddon, but fake internet pharmacies are a growing "global disaster" with increasingly dangerous consequences, pharmaceutical industry figures say.**

The decry follows last week's coroners report over the death of a Canadian woman who dies from metal poisoning after purchasing fake drugs over the internet.

The death and coroners report on 58-year-old Marcia Bergeron, who was found dead in her bed three days after Christmas last year, has thrown the issue of rouge internet pharmacies firmly into the spotlight.

Toxicology reports identified the pills Bergeron bought, including the hypnotic zolpidem, the active ingredient in Sanofi's Ambien which is not legally available in Canada, were the cause of her death, saying the concentration of aluminum in her liver was some 15 times above the expected normal level.

The Bergeron case is one of many recent examples of the counterfeit drug black market infiltrating the bona fide pharma market.

Just two months ago batches of parallel imported fake Zyprexa (olanzapine), Plavix (clopidogrel) and Casodex (bicalutamide) were recalled after they were found to contain less than the required amount of active pharmaceutical ingredient (API).

Last week, Zheng Xiaoyu, the former director of China's State Food and Drug Administration (SFDA) was put to death after he was found to have "sought benefits" for eight pharmaceutical companies by inappropriately approving hundreds of drugs and medical devices between 2001 and 2003. At least six of the products proved to be fake and dozens of people were killed by counterfeit and inferior products in China during his tenure.

Meanwhile, the saga involving diethylene glycol (DEG) contamination of products is ongoing, with the most recent moves being the recall of batches of contaminated toothpaste.

But, pharma industry players are most concerned with the raft of internet pharmacies that offer fake drugs because detection rate is low and the counterfeiting and infiltration is highly sophisticated.

Americas Watchdog chief executive Thomas Martin called the presence of fake internet pharmacies a "global disaster" saying there was upwards of 4000 fake pharmacies and that 90 per cent of products on the internet were counterfeit.

The US consumer advocacy group recently launched the covert operation-like Global Piracy and Counterfeiting Consultants initiative with the aim of stamping out the \$40bn international counterfeit market, but the group has spent the last year involved in behind-the-scenes screening of internet pharmacies, he told US-PharmaTechnologist.com.

Martin feared if the operations were not brought under wraps there was real potential for bioterrorism, especially as he estimated some five million US people bought drugs off the internet because the sites promised anonymity, cheaper prices, and access to drugs currently unavailable in the country or without a prescription.

But the drugs would be marketed differently online to what was sent. Drugs resulting from dodgy cleaning practices, which introduced new chemicals into the drugs, to altering the amount of API or changing fundamental ingredients, were making their way into the patient market, with the most commonly faked drugs being Pfizer's Viagra (sildenafil citrate), Eli Lilly's Cialis (tadalafil) and Bayer's Levitra (vardenafil) - all products for the treatment of erectile dysfunction.

The problem with the sites was *"they change their names as often as you or I change out socks,"* making them very hard to track down, Martin said.

Meanwhile, the drugs were getting into the country easily via a standard yet sophisticatedly modified envelope, he said.

In the past whole pill packets had been posted but now Americas Watchdog had found the drugs were being packaged in a plastic pouch and sealed in flat aluminum packaging before being put into a standard envelope.

*"It's really getting tough because the packaging is perfectly done. It's very difficult for drug sniffing dogs. We think they have got so sophisticated getting into the country that we don't think we can stop it by the mail,"* Martin said.

Earlier this month, the US Food and Drug Administration (FDA) announced its concern over the number of people who continued to buy drugs over the internet.

*"The use of prescription drugs without a prescription is an intrinsically unsafe practice,"* the regulator said in a statement.

The [FDA](#) urged the public to reconsider when looking to purchase drugs over the internet.

Likewise Health Canada has issued a warning on its website following Bergeron's death: *"If you order from these sites, you may get counterfeit drugs with no active ingredients, drugs with the wrong ingredients, drugs with dangerous additives, or drugs past their expiry date. Even if these drugs do not harm you directly or immediately, your condition may get worse without effective treatment."*

The FDA has undergone several investigations into reports of bogus internet sites. In August 2005, the FDA conducted an operation at New York, Miami, and Los Angeles airports which found that nearly half of the imported drugs the FDA intercepted from four selected countries were shipped to fill orders that consumers believed they were placing with "Canadian pharmacies."

Of the drugs being promoted as "Canadian," based on accompanying documentation, 85 per cent actually came from 27 other countries around the globe and a number of the products were found to be counterfeit.

The website Bergeron used to purchase her drugs claimed to be Canadian, and has since disappeared offline.

Reports in local media said the FDA had previously flagged the website as dodgy.

The FDA, who is involved, along with Health Canada and the Royal Canadian Mounted Police, in the ongoing investigation of Bergeron's death, declined to comment when approached by US-PharmaTechnologist.com.

Meanwhile, some big pharma are waking up to the problem, which in some cases is taking more than a \$1m a day from the pockets of pharmaceutical companies.

In May, the chief security officer and vice president of global security at the world's largest pharmaceutical company, Pfizer, addressed Congress about the dangers of the black market, which is threatening to grow to be worth \$75bn by 2010.

Said John Theriault: *"The problem of counterfeit medicines, once thought to be limited to developing countries with weak regulatory systems, is now recognized as a global problem from which no country is immune."*

*"The manufacture of counterfeits is not limited to China and India. They are produced in at least 24 countries, including Canada, the UK, and four other members of the EU - Belgium, the Netherlands, Poland and Portugal."*

Eleven Pfizer drugs are currently targeted by counterfeiters, according to Theriault, and in 2006 more than 8.1 million fake Pfizer tablets were seized, an increase of 20.8 per cent over 2005.

*"In March 2007, we heard of a tragic story of a woman's death which, according to press reports, was caused by drugs she ordered online from a bogus Canadian pharmacy . . . We fear that there may be more terrible stories like this one,"* he said.

*"As Congress develops drug safety legislation, it is essential that you carefully consider this very dangerous situation that has yet to be adequately addressed."*

A US draft law was put before congress in May calling for stronger punishments for drug counterfeiters including a 10 to 20 years prison sentence for counterfeiting offenses that cause serious bodily injury and loss of all proceeds and profits from the illegal activity.

Meanwhile, similar legislative measures have been put before the European Parliament with a positive response in the Parliament's April plenary session in Strasbourg. Under the European proposals, those found guilty of drug counterfeiting (classed as a "serious crime") would be punished with the maximum penalty, a fine of at least €300,000 (\$407,000) and/or four years' imprisonment.

Last year, the Synthetic Organic Chemical Manufacturers Association (SOCMA) of the US and the European Fine Chemicals Group (EFCG) banded together to demand increased regulatory inspections of foreign facilities manufacturing APIs.

Americas Watchdog's Martin believed the problem was becoming too big for government's, industry sectors and companies to control and with the technologies as sophisticated as they were, it made it even more difficult to overcome the problem.

*"The only way to keep counterfeiting in check is to go after these guys,"* he said in reference to the initiative the advocacy group launched, which would involve integrated buy operations to wheedle out the bad guys.

Meanwhile, the National Association of Chain Drug Stores (NACDS) is calling for a hard line approach.

*"NACDS opposes the importation of prescription drugs, which threatens the health and safety of consumers,"* NACDS federal health care programs vice president Julie Khani told US-PharmaTechnologist.com.

*"NACDS and its members are greatly concerned about the patient safety implications of prescription medications sold through rogue internet sites. . . NACDS supports increased penalties for those that engage in the counterfeiting of prescription drugs, and prescription drug pedigree requirements for prescription drugs that have left the normal distribution channel."*

In May, in regards to comments filed with the Senate Judiciary Committee, the association released a statement saying it wanted to work with Congress to eliminate the illegal sites.

*"We believe that the most effective way to guard against these rogue internet sites is to enact narrowly tailored solutions that focus resources on shutting down these illegal suppliers, rather than developing broad policies that sweep up legitimate, state-licensed pharmacies into a federal regulatory scheme that could potentially limit consumer access to state-licensed pharmacies through the internet,"* the statement said.

While technological advances are continually being made to counteract the infiltration of counterfeits into the supply chain, such as radio frequency identification (RFID) tags, and barcodes, there is a strong feeling from the US industry that this will not completely stop the problem, especially if the World Wide Web continues to foster counterfeiters.

Ahead of a US Patent and Trademark Office seminar later this month, Temple University pharmacoeconomist Albert Wertheimer, who will be speaking at the conference on counterfeit pharmaceuticals coming out of China, said in a statement internet pharmacies posed the biggest threat, which were difficult to monitor and regulate.

*"Technology cannot be a permanent, foolproof solution, and only by improving importation and regulation policy can counterfeiting be contained further. The Food and Drug Administration's Counterfeit Drug Task Force believes that attacking the problem through multiple routes will be the most effective way to combat drug counterfeiting."*

But regardless of what decisions are made, what technological advances are achieved, there is one fact that will remain unchanged, as Regional coroner Rose Stanton involved in the Bergeron case told The Globe and Mail: *"What we have is the first person (for whom) we have all the facts, who we know died as a result of these drugs."*

*"But what we also know is lots of people are buying these drugs. So the potential for more deaths is high."*

<http://us-pharmatechnologist.com/news/ng.asp?n=78355-americas-watchdog-fda-internet-pharmacies-counterfeit-drugs-legislative-measures>