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POLICY & POLITICS

BC woman killed by fake drugs bought online

"Metal toxicity" from counterfeit pills reinforces danger of internet meds

BY SAM SOLOMON

At first, BC Coroners Service case number 2006:0143:0117 was something of a mystery. The case involved Quadra Island resident Marcia Bergeron, 58, who was found dead in her bed by a friend last December.

"We had no reasonable cause of death, and she was of an age where sudden death might not be expected," says Vancouver Island regional coroner Rose Stanton, who worked on the file. "There was no evidence of suicide, foul play or trauma. But there were certainly some medications we could not explain or identify." Unmarked packages and bags of pills were found, which turned out to contain the hypnotic zolpidem, which is not available in Canada, the prescription anti-anxiety drug alprazolam and acetaminophen. Coroners Service policy dictates that when drugs are present in an unexplained death, a toxicology examination be conducted. Ms Stanton received the toxicology report in April. "It was quite extensive, as it turned out," she says.

That's putting it mildly. The Burnaby, BC, lab found diphenhydramine (an OTC sedative), acetaminophen, mirtzapine (a prescription antidepressant), dextromethorphan (an OTC cough medicine) and methocarbamol (an OTC muscle relaxant). But most shocking were the dangerously high levels of metals, including aluminum (15 µg/g), phosphorus, titanium, tin, strontium, arsenic and other metals in Ms Bergeron's liver. The level of aluminum alone was 15 times higher than what's considered normal.

So how did Marcia Bergeron end up with a heady cocktail of drugs and metals in her system? More importantly, did they kill her?

ELECTRONIC CLUES

RCMP and US Food and Drug Administration (FDA) officials cracked the case when they took a look at Ms Bergeron's computer in March. She had been visiting websites that sold unlicensed pharmaceuticals — the kind you often see advertised in spam emails. Sifting through her email account, investigators found a series of messages to a friend in which she detailed side effects she was suffering: nausea, diarrhea, aching joints, and eventually hair loss, exhaustion and vision problems. All are consistent with the meds that showed up on her tox screen.

The electronic clues clinched it. The drugs Ms Bergeron bought online were counterfeits; they were manufactured poorly and contained impure "filler" materials. It's since become apparent that the filler was likely contaminated by



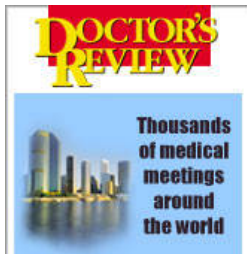
Marcia Bergeron died of metal toxicity caused by counterfeit drugs she bought online

Photo: Handout photo



FDA comparison of real and counterfeit Serostim (somatropin), a human growth hormone used to treat HIV wasting

Photo: FDA



dangerous metals during production in Southeast Asia and sold by a website based in Eastern Europe, possibly the Czech Republic, says Ms Stanton.

With all the pieces of the puzzle finally in place, the BC Coroners Service inquiry wrapped up on July 4. Medical cause of death: cardiac arrhythmia caused by metal toxicity. By what means: ingestion of contaminated counterfeit medication. Classification: accidental.

PUBLIC HAZARD

Ms Bergeron is the first person known to die as a result of ingesting counterfeit meds. For physicians and regulators her sad case is proof positive that drug counterfeiting is a major public health hazard.

"People have been waiting for the canary in the mineshaft," says Ms Stanton. Now they've got one. With Marcia Bergeron, the FDA has finally been able to directly link counterfeiting online pharmacies to a patient's death. Prior cases had all lacked definitive evidence connecting a fatal medication to a website.

Despite the paucity of direct links, it's widely accepted that pharmaceutical counterfeiting is increasing and that there are more ways now than ever before to procure drugs from unlicensed sources. The WHO estimates that between 1% and 10% of drugs sold around the world are counterfeits, and as many as 50% in some countries.

As demonstrated by the Bergeron case, the problem exists in Canada as well. "It's something that everyone has become more aware of," says David W Johnston, president of the Canadian Association for Pharmacy Distribution Management (CAPDM). A 2005 FDA sting operation in New York, Miami and LA airports discovered that almost 50% of drugs shipped to US customers from four selected countries claimed to be from "Canadian pharmacies." In fact, just 15% of them were; the rest came from any of 27 other countries.

CANADA'S RESPONSE

Is Health Canada doing enough to protect patients from the dangers of drug counterfeiting and internet pharmacies that besmirch Canada's good name? "I would say they are almost certainly not," says Dr James Wright, a UBC professor of internal medicine and pharmacology and managing director of the Therapeutics Initiative with an interest in internet pharmacy trends and counterfeiting. "There is almost no precedent, and there is really very little control over it."

In March, the Canadian International Pharmacy Association said Health Canada should rein in those selling fake medication.

But Health Canada spokesperson Alastair Sinclair says the government's Health Products and Food Branch (HPFB) Anti-Counterfeit Strategy for health products is nearly done and will be published in the fall. Health Canada officials have already begun looking at possible changes in legislation, including the federal Food and Drugs Act, to strengthen the government's ability to combat drug counterfeiting. In March, the HPFB sent recommendations to Canadian pharmacists to help them identify counterfeit products, both by ID numbers and visual inspection.

Until the government gets a handle on the issue, says Dr Wright, physicians must be more vigilant. "We are not very good at asking patients what medications they are taking other than what we are prescribing," he says.

For more on medication safety, see "Help patients help themselves with prescription drugs" on page 11.

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