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Health Canada tight-lipped on Champix suicides

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Heidi Clow was on a health kick.

The 22-year-old Canadian navy steward worked out religiously during her foreign deployment with a tactical team that boarded vessels and searched for contraband.

She watched what she ate and studied the labels of any medication she or her friends were taking. When a doctor told her she shouldn't be smoking while on birth control, she decided to try to quit.

She was prescribed Champix, a popular smoking-cessation drug, in June 2009.

Weeks later, when she returned home to Victoria, B.C., Heidi's mother noticed her daughter's trademark smile had disfigured itself into a scowl. She was irritable, short-tempered.

The night Pat Clow last saw her daughter alive, she was smiling again, off to a friend's house for a Saturday night of poker and drinking. The date was Oct. 3, 2009.

Later that evening, alone in her apartment, Heidi ground up Aspirin and sinus medication in a Magic Bullet, mixed them into a protein shake, and killed herself.

A pharmacist notified Health Canada about Heidi Clow's suicide through an adverse reaction report, a tool the federal regulator says it uses to monitor the safety of drugs once they're on the market. For suspected cause, the pharmacist wrote "Champix."

Heidi wasn't the first. A Star investigation has found 24 Canadians taking Champix to quit smoking have killed themselves since it hit the market here in 2007, putting it among the leading suspected causes of reported suicides linked to prescription drugs.

Health Canada has refused to say whether it has investigated cases like Heidi's.

The drug watchdog says it actively monitors side-effect reports, but the Star found no indication Health Canada has investigated individual cases of psychiatric side effects since it looked into 14 cases of aggression, depression and suicidal thoughts from 2007.

Since then, Champix has been linked to nearly 450 serious cases of these same side effects, more than 80 of which ended in hospitalization or disability.

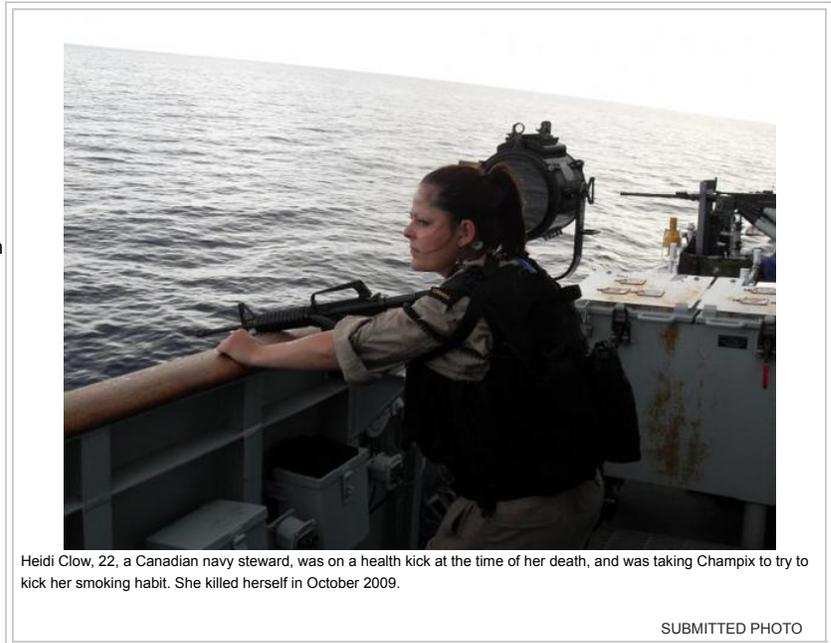
Since then, 24 suicides.

Data analysis by the Star found the number of reported cases of people having suicidal thoughts while taking Champix — about 235 — is nearly three times as high as the next drug.

"When you have something like this, it does behoove investigators to study it more fully and ascertain if, in fact, this signal is accurate," said Dr. Peter Selby, chief of addictions at Toronto's Centre for Addiction and Mental Health.

"This data, if it's lying around some place and not being acted on, then it's just a waste," he said. "That's not a healthy way of getting information out to people."

Pfizer Canada, the drug's manufacturer, and Health Canada say its benefits outweigh the risks, and that side-effect reports show only a suspected connection between a drug and an adverse reaction, but no proof one caused the other.



Heidi Clow, 22, a Canadian navy steward, was on a health kick at the time of her death, and was taking Champix to try to kick her smoking habit. She killed herself in October 2009.

SUBMITTED PHOTO

Selby said Champix is an effective medication, especially for smokers who have tried unsuccessfully to quit through other means to “overcome something that is killing them.”

A spokesman for Health Canada said the regulator has reviewed scientific literature, Pfizer’s clinical data and international cases, and that safety assessments have led to updated safety warnings “clearly outlined” on the drug’s label.

Health Canada told the Star it did a “systematic review” to see if Champix caused psychiatric reactions in 14 cases from 2007, the year the drug came out here.

The regulator later said it “has conducted several systematic reviews of Champix,” but wouldn’t provide details about subsequent cases it investigated or what it found.

The number of adverse reaction reports is a fraction of the more than four million Champix prescriptions that have been filled.

Pfizer is required to forward any adverse reaction reports it receives from consumers and health professionals to Health Canada.

Health Canada acknowledges that side effects are under-reported: reporting — for doctors, nurses and pharmacists — is voluntary. Several medical experts told the Star the federal government should make it mandatory for doctors to report serious side effects.

The Star investigation found Champix had the largest number of reported violent-reaction cases of all drugs.

“The violence cases are often absolutely senseless — anyone who happens to be around,” said Thomas Moore, a senior scientist with the non-profit Institute for Safe Medication Practices, who has studied reported cases of violence linked to the drug in the U.S.

The woman Jeffrey Davidson attacked in October 2010 just happened to be standing outside his Oshawa hospital room.

Davidson, who was on Champix, became paranoid and ended up in a secured room at Oshawa’s Lakeridge Health hospital.

But his delusions followed him. He believed the hospital staff had drugged the water. He had to escape.

He attacked the security guard. He smashed her head into the wall, forced her to the ground and, using both hands, wrenched her head, causing her neck to crack.

Davidson was charged with assault causing bodily harm. In court, a doctor testified that Davidson’s behaviour was the result of an “unfortunate reaction” to Champix and an antibiotic he was taking.

His symptoms stopped after he quit taking both prescriptions.

He was found not criminally responsible and later given an absolute discharge.

The Star doesn’t know what happened after patients stopped taking Champix in the roughly 450 reported cases of suicidal ideation, depression and aggression since the beginning of 2008 because Health Canada is keeping the information secret, refusing to disclose it.

The regulator strips details from the reports before dumping them online in a massive database — including whether the symptoms disappeared after the patient stopped taking the drug.

A newsletter summary of Health Canada’s investigation into the 14 cases from 2007 gives a glimpse into the matter: in eight of those cases, nearly 60 per cent, the patient recovered after stopping the drug.

When Nicki Mclvor started taking Champix, she remembers her cigarettes started to taste “crappy.” She started to feel crappy, too.

“It was like I was sinking into a personal pit of despair,” said Mclvor, 56, who started smoking at 13 and eventually found herself smoking two packs a day.

Driving home one day in May 2008 in rural B.C., she nearly killed herself by turning her Chrysler Intrepid into the path of an oncoming logging truck. She straightened the wheel out at the last moment. She immediately stopped taking Champix.

Mclvor and Heidi Clow’s mother are part of a class-action lawsuit against Pfizer Canada over Champix. An Ontario court has certified the suit but none of the claims has been proven in court. In November, the drug company will seek permission to appeal the court’s decision to certify the case.

In a statement, Pfizer Canada said it “believes that there is no reliable scientific evidence to demonstrate that Champix causes serious

neuropsychiatric events.”

In clinical trials performed by Pfizer before Champix was approved in Canada, researchers found the most common side effects included nausea and abnormal dreams.

A 2009 British study of 80,000 patients found no clear evidence that Champix increases the risk of depression, suicidal thoughts or self-harm compared with other smoking-cessation drugs, although the researchers cautioned that further investigation of the drug’s effect on suicide risk is required. Pfizer said there is an ongoing, worldwide study evaluating the efficacy and safety of Champix in patients with and without mental health disorders.

The decision to award Champix a prestigious pharmaceutical prize in 2009 was largely based on research results provided by Pfizer.

“You have to put yourself back at that time. It’s very easy now to judge four years later,” said Dr. Jacques Gagné, president of Prix Galien Canada’s jury.

He said it was unfair to ask whether jurors would have awarded the prize to Champix had they known of the safety risks now associated with the drug.

“We did what we did with the data that we had at the time that we made the judgment. There’s not more than I can say than that,” he said.

Since the award was given out, the pills have been the subject of several safety warnings in the U.S. and Canada.

In May 2010, Health Canada announced that Champix would carry an explicit warning cautioning that there have been continuing reports of serious psychiatric reactions linked to the drug. That same month, the French government removed Champix from its list of state-covered drugs due to questions over the drug’s safety.

Dr. Andrew Pipe, a smoking-cessation expert at the University of Ottawa’s Heart Institute prevention and rehabilitation centre, called France’s decision unjustified and unsupported by clinical research.

People can get psychiatric side effects when quitting smoking whether they’re using Champix, the patch, or going cold turkey, he said.

“It’s not totally unusual for symptoms of depression, flattened mood, blue thinking, suicidal ideation,” said Pipe, who has done studies and consultant work for the manufacturers of major smoking-cessation drugs.

Several smoking-cessation experts said Champix is an effective medication to help people quit smoking, an addiction that kills more than 37,000 Canadians a year.

It’s believed that it works by stimulating nicotine receptors in the brain, acting like a weaker version of nicotine, while also blocking nicotine from binding to those same receptors.

In doing so, Pfizer says the medicine reduces cigarette cravings and withdrawal symptoms.

In Canada, the drug is reimbursed in B.C., Alberta, Saskatchewan, Manitoba, Ontario and Quebec. The Ontario government has spent about \$7 million covering Champix prescriptions under the Ontario Drug Benefit Plan since it was added to the formulary in August 2011.

The drug company said it is “vigilant in monitoring adverse drug reports for all of its products,” but warned that these reports have “significant limitations” and cannot show if a drug caused a reaction, the incidence of a side effect or how many patients used the drug.

As part of its oversight of Champix, Health Canada has released safety warnings jointly with Pfizer advising people who experience changes in behaviour, aggression, depression or suicidal thoughts to stop taking Champix immediately and talk to their doctor.

Still, doctors say Health Canada should do a better job sharing the information it collects through the side-effect reports.

At the Toronto addictions clinic, Selby continues to prescribe Champix to patients he thinks will benefit from the drug.

But he said the number of serious adverse reaction reports is surprisingly high, adding that the regulator should analyze the reports and share the findings. “It’s pharmacists, it’s physicians, it’s nurse practitioners,” he said. “Anybody who is responsible needs to be able to ... have this information.”

Three years ago today, military police discovered Heidi’s body after she didn’t show up to work.

Her [suicide note](#) is a jumble of apologies and broken thoughts.

"Sorry. I'm cold. I'm done. I'm angry, upset. Let me go . . . I hurt inside," she wrote. "Sorry I gave up. Sorry for being lazy. I love you, mom! Sorry."

Her mother, Pat, chokes up reading the [letter](#). This wasn't her daughter. The Heidi she knew was ambitious and energetic.

"Please! I just want to go. I just want to sleep. Sleep. When will it kick in? I just want the pain to go away."

Clow said her daughter wasn't thinking straight. She wonders if Heidi really wanted to die.

"Sorry I lack the courage to carry on. I just want to fall asleep for this last time. Good night."

She struggles to look at photographs of her daughter.

"I try not to think about it because it still hurts too much to think about it," she said. "I have dreams where I can't find her and I'm looking for her. It's not something that's going away."

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