
Reader's Digest
rdasia.com
"My New Year Wish"
Inspirational Asians Share Their Hopes
Food
Truly Scrumptious!
Festive Foods, Asian Style
&
Cutting Calories With Perfect Portions
"I wish for less anger in society"
- Datin Paduka Sharifah Mazlina -
Adventurer
Plus: Gifts For Tech Lovers
December 2009
Malaysia | RM15
ISSN 0034-0383
9 770034 038003

Going After Goliath

After her husband killed himself, his young widow took on the powerful, global drug company she blames for his death. This is her story

By Mary A. Fischer

Early in 2003 Tim "Woody" Witczak got some good news: a new job, as vice president of sales with a startup energy-efficient lighting company in a heartland American city, Minneapolis, Minnesota. But with the position came stress and difficulty sleeping.

In June, Woody, 37, saw his family doctor, a general practitioner, who gave him samples of Zoloft, an anti-

Kim Witczak, still battling today

depressant that also treated anxiety.

"This was the first time he'd ever been to a doctor about an issue like this," says his wife Kim. "He was a happy person, and had no history of mental illness or depression."

Within a few days, though, Woody experienced several side effects of the drug: night sweats, weight loss, diarrhoea, and trembling hands. His anxiety worsened; he became uncharacteristically irritable and restless. One evening he came home crying after driving around all day. When the samples ran out after three weeks, Woody's doctor doubled his dose to 50mg and urged him to give the drug time.

The instructions from Pfizer, Inc., manufacturer of Zoloft, said it could take four to six weeks to be effective. But two weeks later, Kim recalls, Woody walked in the backdoor with his blue business shirt drenched in sweat. He curled in a foetal position on the kitchen floor, his hands pressing around his head like a vice, and begged: "Help me. I don't know what's happening to me. I think I'm losing my mind. I feel like my head is outside my body looking in."

Less than a week later, Woody seemed to be springing back. He ran three miles, bought airlines tickets for a bachelor party in Las Vegas, and when he spoke by phone one morning to Kim, an advertising account executive who was in Detroit on a short business trip, he suggested they celebrate their tenth wedding anniversary in Thailand. That evening, though, things had changed.

"His voice sounded hollow, like there was nobody there," she remembers. "I just assumed he was busy and distracted. The last thing he said was 'I love you, Kim.'"

Worried, she called Woody the next morning, and kept leaving messages on his mobile phone. Something's not right, she thought. When they were apart, they talked to each other four or five times a day. "Maybe he fell asleep and hit his head," she told her father over the phone. Keith Olson, who lived nearby, left immediately to check on Woody. When he opened the garage door, he saw the unimaginable: Woody was dead. He had hung himself from the rafters.

By cruel coincidence, the *Minneapolis Star-Tribune* ran a front-page story that day: "UK Finds Link Between Antidepressants and Suicide". It was the first Kim and her family learned there might be a connection between Zoloft and Woody's deteriorating condition. Pfizer's side-effect warnings had mentioned nothing about the possibility of suicide nor had Woody's doctor who, like most general practitioners – responsible for prescribing 70 percent of anti-depressants – had no special training in psychiatric conditions and medications. Kim's brother-in-law Eric Swan researched "Zoloft" and "suicide" on the internet and found dozens of websites and blogs presenting evidence, including accounts of suicide victims, which

"Woody was a happy person," says Kim

seemed to support a connection.

"To me, the light went on," Swan says today.

Swan had ventured into an area of major controversy. Most of the medical establishment, as did the American College of Neuropsychopharmacology in 2004, maintained that "the drugs do not pose a risk of suicide." For its part, Pfizer insists to this day that Zoloft, one of the most widely used anti-depressants in the world, does not cause people to kill themselves.

"Pfizer has never seen a signal for suicide with respect to Zoloft," says spokesman Jack Cox, citing a 2006 Food and Drug Administration study that he says, "confirmed the lack of a statistically significant correlation between Zoloft and any suicide-related behaviours."

At the time of Woody's death, millions of consumers were unaware there was any dispute between drug companies, health scientists and bereaved families over the suicide issue. But University of Wales psychologist David Healy says Zoloft and anti-depressants like it increase the risk of suicide three times, even though the overall risk of suicide is still low. Even so, Healy estimates there were about 2000 excess suicides in the United States from 1988, when Prozac was introduced, until 2004. Some of those lives might have been saved, Kim reasoned, if patients had known of the possible dangers.

After much soul searching and

Kim and her sister's husband, Eric Swan, triggered a lawsuit against the drugmaker

prayer, Kim decided she wanted to dedicate herself to making drug safety laws tougher, to give meaning to Woody's death. It seemed unfathomable to her that her husband would kill himself. She says it made no sense that he did not leave a note. Furthermore, he loved life: He was always a man in motion, running laps around a lake near their home in Minneapolis, taking vacations to Europe and Australia, going on camping trips. She created a website – woodymatters.com – and started a crusade to force drug manufacturers and the US Food and Drug Administration (FDA) to add more comprehensive safety warnings on Prozac, Zoloft, Paxil and other anti-depressants known as selective serotonin reuptake inhibitors (SSRIs).

"Woody was gone," says Kim today, "but I wanted to save other people's lives. Woody never got to have children, so I wanted this to be his legacy."

Anti-depressants as a whole generated revenues of just over $20 billion worldwide in 2008, according to IMS Health, a Connecticut research company that tracks drug sales. The anti-depressants normalise chemical abnormalities in the brain by adjusting levels of serotonin and norepinephrine that affect feelings of anxiety, irritability, sadness, fatigue and depression. Millions of people – from the very young to the very old – have taken these drugs.

Kim has testified at more than 40 Congressional drug safety hearings in Washington since 2004 , telling the story of how her easy-going husband came to commit suicide.

Eventually her battle took her into US federal court. In 2004, she sued Pfizer, Inc., alleging that the company did not sufficiently warn doctors and patients about the drug's potential to cause suicidal tendencies, a claim Pfizer disputes.

"The Zoloft label fully complies with all FDA-mandated requirements," says company spokesman Jack Cox. The problem, Kim's lawyers argued, was that the Zoloft label did not comply with the state of Minnesota's much-stricter consumer protection laws. Pfizer countered that a state could not pre-empt federal regulations. However, in a landmark decision, US Chief District Court Judge James M. Rosenbaum ruled that it could. "Federal labelling laws are minimum standards," he wrote in July 2005. "They do not necessarily shield manufacturers from state law liability."

Rosenbaum allowed Kim's case to go to trial. But before there was a verdict, she and Pfizer settled for an undisclosed amount. The judge also made public numerous corporate documents showing that both drug companies and federal regulators were aware of a possible connection between SSRIs and suicide from the earliest days of Prozac. Kim took those documents to Washington.

When she appeared before FDA regulators in 2005, she was nervous but confident her presentation correctly pinpointed the agency's drug review shortcomings. In her testimony, she presented cases and studies showing that pharmaceutical companies or the FDA knew about the risks of suicidality (suicidal thoughts or behaviour) for both children and adults treated with anti-depressants, but took no action.

Her criticisms were shared by a number of FDA insiders, including David Ross, then a senior member of the agency's Office of New Drugs. "Her case was a clear example of an agency captured by the industry it is supposed to regulate," explains Ross.

After the hearings, the FDA agreed to require pharmaceutical companies to put black box warnings – used only when a drug has serious or life threatening effects – about the risk of suicide in SSRIs for patients in the US up to the age of 25. This extended a black box warning that had been added in 2004 about the possibility of suicide in children. It was an important step, but Kim wasn't satisfied: "Woody was 37, and there are many cases in which suicide victims were in middle age."

Kim is continuing to campaign for a more comprehensive age drug-warning label – and is now in a position to have her voice heard. Last March, the FDA appointed her as patient representative on the agency's advisory review committee, a job that keeps her busy. She travels to Washington at least ten times a year to testify about various drugs.

"I used to get mad at God," she says. "But I now understand why it needed to be someone like Woody, someone happy and not depressed, to make sure the problems with these drugs couldn't be ignored." ■