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The battle for Woody; A widow says a suicide warning on antidepressant Zoloft might have saved her husband's life.

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Two years after her husband hanged himself in their garage, there has been no closure for Kimberly Witczak.

And there won't be until she's done pursuing those she thinks are responsible for Tim (Woody) Witczak's death at 37. There was no suicide note, but for Witczak, there was something equally damning - a partially consumed bottle of the antidepressant Zoloft on the kitchen counter of their south Minneapolis home.

Since then, Witczak, 39, has been on a crusade that has taken her to a federal courtroom in Minneapolis, the hallways of the U.S. Capitol and the headquarters of the Food and Drug Administration in Rockville, Md.

She currently is in federal court challenging Pfizer Inc., the maker of Zoloft and the biggest pharmaceutical company in the world. She contends that Pfizer did not sufficiently warn doctors and patients about the drug's potential to cause suicidal tendencies, a claim that Pfizer denies.

Hers is not the only suit against Pfizer involving Zoloft - there are at least a dozen cases around the country. But it's one of a handful to invoke a state "failure to warn" statute, with Witczak asserting that the state law should supersede even FDA requirements on disclosure.

Already, her testimony before FDA advisory committees has been among those voices that forced drug companies to include warnings that certain antidepressants can cause suicidal thoughts in those under 18. That's not enough for Witczak; she wants the stronger warnings to cover adults, too.

Connections to suicide

Her case hinges on an assembly of corporate documents collected in earlier lawsuits involving Zoloft and similar antidepressants. The papers suggest that as far back as the mid-1980s, manufacturers and regulators saw connections between a family of drugs known as selective serotonin re-uptake inhibitors (SSRIs) and suicidal tendencies.

A 1991 Pfizer document, for example, reported how a 52-year-old patient "became acutely suicidal" 13 days after he started taking sertraline (Zoloft) and that his condition improved once he stopped taking the drug. A 1993 confidential Pfizer document reported that a 45-year-old woman had to be hospitalized after she developed akathisia while on the drug. Akathisia is a neurological development that results in extreme agitation that can lead to suicide.

Zoloft was introduced in 1992 and quickly became a blockbuster drug for Pfizer. The drug had \$3.3 billion in sales in 2004. Besides depression, doctors also began prescribing it for "off-label" uses such as migraines and moodiness. Tim Witczak was one of those who had no symptoms of depression but was given a prescription for Zoloft by his doctor for insomnia.

Pfizer said clinical trials and studies and reports fail to demonstrate a connection between use of Zoloft and suicide.

"There's no scientific link to Zoloft and suicidal behavior. That's the long and short of it," said Bryant Haskins, a Pfizer spokesman. "Zoloft has provided effective and life-saving treatment to millions of patients since it's been on the market."

Others note that Zoloft is a crucial drug in the arsenal against major depression, a serious disease in the United States.

"Do we shoot ourselves in the foot if we don't treat this catastrophic illness?" asked Dr. Paul Goering, medical director for the psychiatry department at St. Paul's United Hospital. "If we didn't have them [antidepressants], I don't know what I'd do."

Goering said 10 percent of all untreated patients with major depression commit suicide.

He said antidepressants should be prescribed after a thorough conversation between doctor and patient and ongoing monitoring for side effects. "If you start to

see or feel these things [suicidal thoughts], then let us know right away," Goering said.

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Prescription for insomnia

Witczak disputes assertions that her husband, Tim - Woody to his friends - must have been depressed to commit such an ultimate act. He was given Zoloft for insomnia as he immersed himself in a new, high-level sales job.

"I went to two suicide support groups. They said it was undiagnosed depression. I could accept that if I thought that was true. But it wasn't," Witczak said, describing her husband of 10 years as an outgoing, caring "kid at heart."

Witczak has been an effective spokeswoman for her cause.

"She's very articulate and has a very compelling story to tell," said Karin Hope, legislative aide to U.S. Rep. Jim Ramstad, R-Minn., who has arranged for Witczak and her brother-in-law, Eric Swan, to meet with congressional committees that have jurisdiction over the FDA and drug safety.

"We were dealing in the abstract until we came in touch with her," said U.S. Rep. Maurice Hinchey, a New York Democrat who has been battling the FDA over drug safety issues. "She put a human face on the things we are trying to correct."

Last October, the FDA ordered drug manufacturers to place "black box" warnings on all antidepressants to warn doctors and patients about the increased risk of suicidal thoughts and actions for children and adolescents taking the drugs. The FDA issued the directive based on the findings of advisory committees before which Witczak testified.

The FDA currently is asking pharmaceutical companies for clinical studies of adults and suicide rates when using an antidepressant. "We've just begun collecting data. It will take awhile to evaluate," FDA spokeswoman Susan Cruzan said.

Witczak and Swan have enlisted the help of Los Angeles attorney Karen Barth Menzies and her law firm, Baum Hedlund. Barth Menzies has 12 Zoloft cases pending across the country and has filed lawsuits involving other antidepressants in two dozen states.

Among the Zoloft cases handled by the Baum Hedlund firm and Barth Menzies was the 1998 murder of comedian Phil Hartman by his wife, Brynn, who then committed suicide. Tests later showed she had ingested Zoloft, cocaine and alcohol on the day of the shootings.

Barth Menzies filed a suit on Witczak's behalf against Pfizer in May 2004. A motion by Pfizer is pending to dismiss the lawsuit on the grounds that Minnesota state law cannot supersede the FDA's authority to regulate drug safety. Witczak, with the court assistance of state Attorney General Mike Hatch, contends that Pfizer failed to sufficiently warn users of Zoloft about the suicide connection.

In an affidavit filed in the Witczak case opposing Pfizer's dismissal motion, Dr. David Healy - a British psychiatrist and believer in the SSRI-suicide link - asserts that Pfizer knew of Zoloft's risk for more than 10 years. Healy is the author of a book published last year titled, "Let Them Eat Prozac."

"Pfizer has been far from fully forthcoming with the FDA about the adverse reactions of Zoloft, which can lead certain vulnerable patients to become suicidal," Healy said in the affidavit dated March 14, 2005.

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A birthday meeting

The Witczaks met in Chicago on Kim's birthday, June 1, 1990. She was working at an ad agency there and later became a producer for the Jenny Jones syndicated talk show; he was in sales for an Anheuser-Busch distributor. They married in 1993 and moved to the Twin Cities in 1994 for Woody's sales career. Kim eventually became an account manager for Fallon Worldwide, a Minneapolis advertising agency.

In May 2003, Woody got involved in a startup company as vice president of sales. The company sold energy-efficient lighting to commercial and industrial customers. Witczak said he was excited about being part of something from the ground up.

Anxiety over the new job and the new business caused Woody to have trouble sleeping, Witczak said, and his family doctor prescribed Zoloft. For the next two weeks Kimberly Witczak was on assignment in New Zealand. Back home, Woody experienced night sweats, diarrhea and physical agitation.

One evening shortly after Witczak returned from New Zealand, she was in the kitchen when Woody entered after aimlessly driving around town.

"He was drenched. He'd been driving all day. He sat on the kitchen floor in a fetal position and said, 'Kim, you gotta help me. My head's outside my body!'" she recalled.

Kim calmed Woody down, and things seemed to go smoother, although he complained about gruesome nightmares that he refused to describe.

On Monday, Aug. 4, Witczak left for an assignment in Detroit. She talked to Woody on Tuesday morning and described him as excited from a successful sales call. They booked a flight to St. Louis for a friend's wedding in October and Woody booked a separate flight to Las Vegas for a bachelor party the following weekend. When Witczak called late Tuesday, there was a different Woody on the phone, she said. He seemed "completely distracted. He was in a different state of mind."

When Witczak failed to reach Woody by phone or e-mail on Wednesday, she asked her father to go to the house. That's when Woody was found dead, hanging in the couple's two-stall garage. One of his last acts had been to search Google on the word "noose."

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WHAT IS IT?

Zoloft is the brand name for the antidepressant sertraline. It is part of a class of antidepressants called selective serotonin re-uptake inhibitors (SSRIs). Other branded drugs in that class include Prozac and Paxil.

Zoloft 2004 worldwide sales: \$3.36 billion

Source: Medical Ad News

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