Was Traci Johnson driven to suicide by anti-depressants? That's a trade secret, say US officials

Researchers trying to establish the truth about a new drug - now on sale in the UK - are being thwarted by a government agency whose job is to protect the public

By Jeanne Lenzer and Nicholas Pyke

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When the body of a 19-year-old student, Traci Johnson, was found hanging from a shower rod in the laboratories of pharmaceuticals giant Eli Lilly, US officials were quick to announce that the death could not be linked to a new anti-depressant drug she was helping to test.

During her stay at the hotel-cum-clinic in Indiana known as the Lilly Lab, Johnson had been taking part in trials for a secret new formula called Cymbalta, a chemical cousin of Prozac, which the company hoped would guarantee huge profits for years to come.

For the drugs giant, her death on 7 February last year was an "isolated tragedy" that did not prevent it from pressing ahead with the Cymbalta trials. It is now on sale in the US and - under another name - in Europe and the UK.

But for the scientific community it was another warning bell about a class of medicines already under scrutiny for possible ties to suicide. After all, Johnson was not depressed. Far from it. She enrolled in the clinical trial as a healthy volunteer in order to earn money to pay for her college tuition. Anyone with signs of depression was excluded.

Now, medical researchers attempting to establish the truth about Cymbalta are asking why her disturbing and very public suicide is completely absent from the official record, at least as it is released to academics and the public. According to an investigation by The Independent on Sunday, this and at least four other suicides by volunteers have been hidden by the US regulators, the Food and Drug Administration (FDA).

As the FDA admits, even a young woman's death counts as a commercial secret in the world of pharmaceuticals.

Last week, the IoS reported how vital data on prescription medicines found in millions of British homes has been suppressed by the US authorities, even though the information could potentially save lives. As a result, medical specialists say they have been unable to assess the true risks of big-name products such as painkillers Vioxx (now withdrawn) and Neurofen.

It is hard to overestimate the importance of Cymbalta to Eli Lilly. Prozac, the popular antidepressant that accounted for a quarter of the company's $10bn revenues in 2000, went off-patent in August 2001, causing a bruising financial reaction on Wall Street. In just one day, the company's stock plunged by almost a third.

The replacement was supposed to be Cymbalta, which financial analysts predicted would bring

in a whopping $2bn in sales.

Lilly defended its drug, saying that 4,142 depressed patients had taken Cymbalta and the deaths represent a 0.097% suicide rate. Besides, it said, it is the underlying depression - not the drug - that causes sufferers to become suicidal.

With so much at stake, the FDA sent experts to Indianapolis to investigate. When they announced that Cymbalta "couldn't be linked to her death", her family was outraged. According to the Johnson family spokesperson, Pastor Joel Barnaby, FDA officials never spoke to them.

National headlines following the FDA ruling were unequivocal. The Associated Press ran an article entitled, "FDA clears Lilly drug in suicide". And six months after Johnson's death, the FDA approved the drug for the treatment of depressed patients. Cymbalta, which has the chemical name duloxetine, is also sold for "stress urinary incontinence" in Europe and the UK under the trade name Yentreve.

Beginning in January, the IoS started filing US Freedom of Information Act requests for all safety data relating to the drug's use. The FDA responded with its Adverse Events Reporting System (Aers) database, which shows 13 suicides reported among patients taking duloxetine and about 41 deaths. Five suicides are notably absent from the information supplied by the FDA; that of Johnson and the four patients who committed suicide while enrolled in clinical trials of Cymbalta.

The FDA has a good reason not to release any information about these five patients: they don't have to. In fact, it's against the law, according to Dr Robert Temple, its director of medical policy. In an exclusive interview with the IoS, he said that some of the data filed by Lilly is considered commercially protected information.

When asked whether the FDA would release all the data from anti-depressant trials analysed by the FDA to a researcher, Dr Temple said his belief is that "the answer is clearly no". That, he said, is something "only Congress can change".

Dr David Graham, associate safety director at the FDA, agreed with Dr Temple that it would take action by Congress to make data available that are currently considered trade secrets. "Most of us think of trade secrets as a manufacturing process or the names of certain ingredients, but here, deaths are being considered trade secrets."

Following revelations that drug companies were not publishing negative data, Eli Lilly won praise for its announcement that it would disclose all clinically relevant trial data on its website. The company has stated that it will disclose "all medical research results that are significant to patients, health care providers or payer - whether favourable or unfavourable to a Lilly product".

The company posts clinical trials results on its freely available clinical trials website (www.lillytrials.com). Data from seven trials of duloxetine are posted, but these show a total of two deaths associated with duloxetine, and no reported suicides. Lilly says that it is "on track" to post all clinical data by 1 July 2005.

A spokesman for Eli Lilly, David Shaffer, said some of the studies are still in progress and that

the suicides would be reported when the studies are completed, the data is reviewed and, if applicable, they have been published in a peer-reviewed scientific journal. Other suicides occurred in depression studies "run by another company". Two cases from a completed study will be posted by 1 July, he said.

Dr Jerome Hoffman, professor of medicine and emergency medicine at the University of California at Los Angeles said, "Like Dr Temple, I don't know whether this one young woman's death was related to this drug, nor do I believe that it's possible for anyone to determine that with certainty."

But he said it was "unconscionable" that "the FDA appears to be prevented by law from carrying out what we all surely believe is its primary role in this process, which is to safeguard the interests of the public.

"The fact that the law not only does not make this a requirement - of the drug company itself, no less of the FDA - but that it actually makes it forbidden, clearly turns the function of this government agency on its head: from protector of the public health, to protector of industry."