

FDA to review "missing" drug company documents

The US Food and Drug Administration has agreed to review confidential drug company documents that went missing during a controversial product liability suit more than 10 years ago. The documents appear to suggest a link between the drug fluoxetine (Prozac), made by Eli Lilly, and suicide attempts and violence.

by Jeanne Lenze, New York ([BMJ2005:330:7 \(http://bmj.bmjournals.com/cgi/content/full/330/7481/7?ehom \)](http://bmj.bmjournals.com/cgi/content/full/330/7481/7?ehom))

(article continues...) The missing documents, which were sent to the BMJ by an anonymous source last month, include reviews and memos indicating that Eli Lilly officials were aware in the 1980s that fluoxetine had troubling side effects and sought to minimise their likely negative effect on prescribing.

The documents received by the BMJ reportedly went missing during the 1994 Wesbecker case that grew out of a lawsuit filed on behalf of victims of a work-place shooting in 1989. Joseph Wesbecker, armed with an AK-47, shot eight people dead and wounded another 12. He then shot and killed himself. Mr Wesbecker, who had a long history of depression, had been placed on fluoxetine one month before the shootings.

One of the internal company documents, a report of 8 November 1988, entitled "Activation and Sedation in Fluoxetine Clinical Trials," found that in clinical trials "38% of fluoxetine-treated patients reported new activation but 19% of placebo-treated patients also reported new activation yielding a difference of 19% attributable to fluoxetine."

The FDA recently issued a warning that antidepressants can cause a cluster of "activating" or stimulating symptoms such as agitation, panic attacks, insomnia, and aggressiveness. Dr Joseph Glenmullen, a Harvard psychiatrist and author of *The Antidepressant Solution*, published by Free Press, said it should come as little surprise that fluoxetine might cause serious behavioural disturbances, as it is similar to cocaine in its effects on serotonin.

Dr Richard Kapit, the FDA clinical reviewer who approved fluoxetine, said he was not given the Lilly data. "These data are very important. If this report was done by Lilly or for Lilly, it was their responsibility to report it to us and to publish it." ... ([full article \(http://bmj.bmjournals.com/cgi/content/full/330/7481/7?ehom \)](http://bmj.bmjournals.com/cgi/content/full/330/7481/7?ehom))

(addendum --- a few days according to Associated Press)

Lilly Says Prozac Documents Contain No New Information

by Tom Davies, The Herald-Dispatch, 5 Jan 05, [full article \(http://hosted.ap.org/dynamic/stories/L/LILLY_PROZAC?SITE=WVHUN&SECTION=HOME&TEMPLATE=DEFAULT \)](http://hosted.ap.org/dynamic/stories/L/LILLY_PROZAC?SITE=WVHUN&SECTION=HOME&TEMPLATE=DEFAULT))

INDIANAPOLIS, Jan. 5 (AP) - Eli Lilly & Company said Wednesday that internal documents about the safety of its popular antidepressant Prozac - reported in a British medical publication to be long missing - were given years ago to federal regulators and to lawyers suing the company...

