The Eli Lilly Prozac Suicide and Violence Documents An Analysis by Peter R. Breggin, M.D.

The <u>British Medical Journal</u> (BMJ) has now released to the FDA and to members of the U.S. Congress a series of documents that were lost after the 1994 Wesbecker trial in which I testified against Eli Lilly and Company concerning Prozac-induced murder and suicide (1). Joseph Wesbecker had been taking Prozac and became psychotic shortly before shooting and killing himself and eight co-workers. I am familiar with these documents because I initially found them in the early 1990s while searching through mountains of paper produced by the drug company in the discovery process. At the time I was the scientific expert for the combined Prozac suits and one of my tasks was to evaluate Eli Lilly's discovery materials for all the initial cases, including the 1994 Wesbecker trial (1). At the Wesbecker trial I testified about each of the documents now in the possession of the BMJ.

Paul Smith, the attorney for the plaintiffs, secretly settled the case during the trial and then denied the fact to presiding Judge John W. Potter. The plaintiffs agreed to water down their presentation of the case to the jury in return for a large secret settlement. After Eli Lilly seemed to win the trial by a 9-3 vote, Judge Potter found out that the trial was a sham aimed at exonerating the drug company. The Supreme Court of Kentucky declared that Eli Lilly may have committed "fraud" and that the drug company had "manipulated" the judicial system. The judge voided the jury verdict and changed it to "settled with prejudice" by Eli Lilly. Although the initial "victory" by Eli Lilly was widely covered in the press, the change in the verdict was largely ignored.

After the trial, many of the Eli Lilly documents disappeared. Simultaneously, Eli Lilly began to deny the existence of these documents and continued to withhold them from the FDA and the medical profession. Unless someone had heard my testimony, read the transcript, read my subsequent books and articles (e.g., 1 and 2), or talked to me about the case, they would not have known that these important documents existed.

The following analysis summarizes my testimony about these documents in the Wesbecker trial (1). The missing Eli Lilly documents now in possession of the BMJ can be divided into four groups:

The first group is a study of "Activation and Sedation in Fluoxetine Clinical Trials" that reports the 38% rate of stimulation in the patients, even though many of the patients were sedated and even though many parameters of stimulation were not counted. This study was requested by the German drug regulatory agency but Eli Lilly withheld the study and never gave it to the Germans or to the FDA.

The second group of documents is a 1985 in-house analysis by Eli Lilly in which the company found a large statistically significant increase in suicide attempts for patients taking Prozac during their placebo controlled clinical trials. Twelve suicide attempts were found in the Prozac group and only one each in the control group and the comparison drug, a tricyclic antidepressant. Even after the company winnowed out six of the suicide attempts, the remaining 6:1 ratio was alarming. Furthermore, Eli Lilly hid many of their Prozac-related suicide attempts under false categories (see ahead). Like the

activation study, Eli Lilly withheld the suicide study and did not turn it over to the German regulatory agency or to the FDA.

The third group of documents involves a study conducted by the FDA concerning increased spontaneous postmarketing reports of "hostility" and "intentional injury" on Prozac. The FDA used a comparison antidepressant, trazodone, as a control. The FDA found a relative increase of reports of hostility and intentional injury per prescription of Prozac compared to trazodone. The spike in Prozac reports occurred even before any public controversy surrounding Prozac and violence. After the Wesbecker trial, I repeatedly attempted to obtain the FDA study through Freedom of Information Act (FOIA) requests. The FDA finally told me that these documents were lost.

The fourth group of documents includes in-house Eli Lilly memoranda showing that the company consciously hid Prozac-induced suicidal acts under misleading categories, such as "no drug effect," so that they remained undisclosed to the FDA. In one memo, an Eli Lilly employee expresses shame and regret about hiding this data. I also testified about these memoranda in the Wesbecker trial.

In summary, I based a central portion of my testimony in the Wesbecker case on the Eli Lilly documents now in the possession of the BMJ. After the trial, with its secret agreement between the plaintiffs and the drug company, the documents once held by plaintiffs' attorney Paul Smith could not be recovered by other attorneys or their experts. As already noted, I continued to describe and analyze the Eli Lilly documents in my books and articles (e.g., 2, 3). I also continued to cite them as a medical expert in product liability lawsuits against Eli Lilly. However, the drug company has reached sealed settlements in every Prozac product liability case in which I have been an expert. In this manner the company has avoided making the documents public in a trial.

A complete transcript of my testimony in the Wesbecker case can be found on my website: http://www.breggin.com/wesbeckertestimony.html.

- (1) Breggin, P. Testimony in Joyce Fentress et al. vs. Shea Communications et al. [The Wesbecker case]. Jefferson Circuit Court, Division I, Louisville, Kentucky. No 90-CI-06033. Volume XVI. <u>Click here for Breggin testimony.</u>
- (2) Breggin, P., <u>Brain-Disabling Treatments in Psychiatry</u> (Springer Publishing Company, New York, 1997). The Lilly documents are discussed in this medical book.
- (3) Breggin, P. "Suicidality, violence and mania caused by selective serotonin reuptake inhibitors (SSRIs): A review and analysis." <u>International Journal of Risk and Safety in Medicine, 16</u>: 31-49, 2003/2004. The Lilly documents are discussed in this peer-reviewed journal article. <u>Click here for Breggin article</u>.

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