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Letter to the British Medical Journal (BMJ)

Dr. Breggin Discusses the Eli Lilly Prozac Documents

In his letter to BMJ on January 1, 2005, attorney Jerrold Parker agrees about the importance of the Eli Lilly documents now in the possession of the BMJ and their incriminating nature in regard to the drug company. However, Parker makes an error when he says that Eli Lilly never disclosed the documents. In fact, I initially found the Eli Lilly documents 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. If Attorney Jerrold Parker had heard my testimony or read the transcript, he would have known that the documents had been disclosed in the Wesbecker trial.

Paul Smith secretly settled the case during the trial and then denied the fact to presiding Judge John W. Potter. When Judge Potter found out that in effect the trial was a sham, the Supreme Court of Kentucky declared that Eli Lilly may have committed "fraud" and that the company "manipulated" the judicial system. The judge changed the jury verdict to "settled with prejudice" by Eli Lilly.

After the trial, the Eli Lilly documents in possession of Paul Smith 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 the documents ever existed.

The Eli Lilly documents now in possession of the BMJ are copies of the documents that I used as the basis for my testimony in the Wesbecker case and indeed have my handwriting on them. These documents 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. Their disappearance was so thorough that other attorneys in the consortium of combined Prozac suits, such as Jerrold Parker, apparently did not know that they ever existed. 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: www.Breggin.com.

(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. Available on www.Breggin.com.

(2) Breggin, P., Brain-Disabling Treatments in Psychiatry (Springer Publishing Company, New York, 1997).

(3) Breggin, P. “Suicidality, violence and mania caused by selective serotonin reuptake inhibitors (SSRIs): A review and analysis.” International Journal of Risk and Safety in Medicine, 16: 31-49, 2003/2004.

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