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**An Examination of Eli Lilly and Company's Contentions that the BMJ  
Prozac Documents were Never Missing and Have No Significance**

**A report by Peter R. Breggin, M.D.**

The BMJ recently received a series of in-house Eli Lilly documents concerning Prozac from an anonymous source. The BMJ then forwarded the documents to other authorities, including Congressman Maurice Hinchey and the FDA. Congressman Hinchey then distributed the documents to other individuals and organizations, including Dr. Peter Breggin, who received them as four digital folders.

After examining the documents sent to Congressman Hinchey, Dr. Breggin has confirmed their authenticity. Dr. Breggin originally found, examined and evaluated each of these documents in the early 1990s when he was the plaintiffs' medical and scientific expert for the combined Multi-District Litigation (MDL) concerning Prozac. He testified about these documents in the Wesbecker case in 1994 after which the documents disappeared from view (see below).

Numerous sources have now expressed public concern that the drug company seemingly withheld these documents concerning Prozac-induced activation (stimulation), suicidality and aggression.

Eli Lilly has criticized BMJ for releasing the documents. The drug company claims that these documents and/or the data in these documents were given to the FDA and otherwise made available, and that there is nothing new or important contained in them. This report evaluates and analyzes the drug company's claim that they did not hide these documents and that they contain nothing new and nothing with grave public health implications.

**I. Brief Description of the Documents**

The missing Eli Lilly documents released by the BMJ can be divided into four groups:

The first group is a study of "Activation and Sedation in Fluoxetine Clinical Trials" dated 11.8.88 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. This document is located in the fourth and last digital file.

The second group of documents is a July 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. This study is found in the first three of four files.

The third group of documents involves a study conducted by the FDA concerning increased spontaneous postmarketing reports of “hostility” and “intentional injury” on Prozac. These documents were generated shortly before the 1991 FDA PDAC meeting that evaluated antidepressant-induced suicidality. The FDA used a comparison antidepressant, trazodone, as a control. The FDA found a large twenty-fold 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. Before and after the Wesbecker trial, Breggin repeatedly attempted to obtain the FDA study through the Freedom of Information Act (FOIA) requests. The FDA finally wrote him that the documents could not be found. This group of documents is contained in the fourth file. These documents also contain graphs showing a large forty-fold relative increase in reports of suicide attempts, overdose and psychotic depression on Prozac compared to trazodone.

The fourth group of documents includes in-house Eli Lilly memoranda by Claude Bouchy written in November 1990 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. The memos are found in the fourth file.

## **II. The History of the Documents Distributed by the BMJ**

All of the documents circulated by the BMJ through Congressman Hinchey originated during the discovery process for a series of product liability suits against Eli Lilly (the MDL cases) in the early 1990s. Dr. Breggin was selected as the scientific expert to evaluate the discovery materials and other relevant scientific sources on behalf of all the attorneys in the combined suits.

In the Multi-District Litigation (MDL) an Indianapolis court had combined more than two hundred product liability suits against Eli Lilly concerning Prozac-induced suicide and violence. The MDL was not a class action suit. Instead, individual suits were combined for the purpose of discovery so that each attorney would not have to re-invent discovery for each case.

The Wesbecker (Fentress) case was the first of the MDL cases. Texas attorney Paul Smith who was the chair of the MDL team brought the case. As the medical and scientific expert who reviewed all the available discovery materials, Dr. Breggin

organized, analyzed and testified about each of these documents at the trial in 1994. His testimony in the case can be found on his website ([www.Breggin.com](http://www.Breggin.com)). However, following the trial, the documents disappeared from view again. The plaintiffs and Eli Lilly secretly settled the case during the trial but denied it when asked by the judge.

As a part of the settlements, the plaintiffs offered the jury a watered down case, enabling Eli Lilly to win by a 9-3 jury vote. Presiding Judge John Potter later realized the trial had been a sham. The Kentucky Supreme Court found that Eli Lilly might have committed “fraud” and that it “manipulated” the court system. The judge was empowered to vacate the verdict and he declared that Eli Lilly had settled the case with prejudice. However, by that time many of the other suits against the drug company had been dropped or settled to the advantage of Eli Lilly on the mistaken notion that the company had won a fair trial and that no incriminating documents existed.

After the trial the judge, John W. Potter, raised a series of ethical questions about the trial that apparently remain unanswered in a court of law.<sup>1</sup> He asked, “Should the court have been advised that Lilly agreed to pay substantial sums in consideration for the plaintiffs not introducing evidence?” and “May an attorney limit the zeal with which he pursues a claim at trial in return for a monetary consideration paid by his opponent?”

All of the Eli Lilly documents were marked for identification with PZ numbers as a part of making them available in the discovery process for the multi-district litigation. The drug company contends that this proves that it made the documents available. However, these materials were obtained under seal through discovery during contentious legal proceedings and then kept from reaching the public domain through multiple secret sealed settlements starting with the Wesbecker case. Dr. Breggin has been an expert in numerous additional product liability cases against Eli Lilly involving suicide and murder and each time the company has settled and kept the documents sealed. The company did everything it could to keep them from becoming available.

Probably as a part of the secret settlement in the Wesbecker case, most of the documents given to the BMJ were never made into exhibits or entered into evidence in the Wesbecker trial, so they never became available after the trial. They were never made public, provided to the FDA, or published by Eli Lilly. Drawing details from his own testimony, Dr. Breggin has discussed all of these documents in his books and peer-reviewed articles.

As already noted, Eli Lilly claims that the data in these documents were given to the FDA and otherwise made available. The documents, however, are much more than the data contained in them. They are highly organized evaluations showing increased activation, suicidality, and aggression on Prozac. The FDA is not required to make its own evaluations of drug company data and instead reviews evaluations that are the responsibility of the drug company. Even if the data contained in these documents were somewhere included in the thousands of New Drug Application (NDA) pages sent to the FDA, the organized analyses were not, and the FDA would not on its own organize the data for analysis.

Here are some additional points in regard to Eli Lilly’s claim that it has made the documents or data available:

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<sup>1</sup> Judge John Potter, Notice and Order in *Joyce Fentress, et al. v Shea Communications et al.*, Jefferson Circuit Court, Division Five, March 17, 1997.

(1) Lilly never sent the following documents to the FDA: The Activation Study, the Suicide Study (the first three files), and the two Bouchy Memos. The FDA at one time possessed the graphs and tables concerning increased reports of “Suicide Attempts, Intentional Overdoses and Psychotic Depression” and “Hostility and Intentional Injury” but later could not produce them. Therefore, Eli Lilly remained the only organization in possession of each of the documents.

(2) All 28 boxes of discovery material from the Wesbecker case (including the documents distributed by the BMJ) were returned to Eli Lilly by Paul Smith, thus depriving the multi-district litigation team from having them.<sup>2</sup> These documents should have been returned to the multi-district team of attorneys and Judge Potter raised ethical questions about Smith’s actions in sending them back to the company. Attorney Nancy Zettler in Chicago, who assisted Paul Smith at the Wesbecker trial, claims to have the discovery documents from the MDL available in a warehouse, but plaintiff’s attorney Andy Vickery doesn’t believe that these include the 28 key boxes winnowed out for the Wesbecker case. Also, Zettler’s documents are sealed and therefore secret. Dr. Breggin has never met an attorney who was aware of their existence until informed by him based on his experience as the medical expert in the multi-district cases.

(3) It bears re-emphasizing that the only possible way to get these documents has been through aggressive, expensive legal efforts and in each case they have remained sealed.

(4) Reporters have sometimes contacted Eli Lilly after reading references to these documents in my books, articles and speeches. The company has informed them that the documents do not exist. .

(5) Former multi-district litigation attorney Jerrold Parker, wrote to BMJ.com that he didn’t know these documents existed. He believed they hadn’t been produced by Lilly in the initial discovery process. In other words, the documents had so completely disappeared from view that one of the MDL attorneys never even knew they existed.

(6) Eli Lilly never published the spontaneous reporting system data concerning suicide and violence developed with the FDA and later missing from the FDA. In this one case at least, the FDA had the data because it was taken from the agency’s own spontaneous reporting system files. But the graphs and tables, that is, the organization of the data, were key. They showed the huge increase in spontaneous reports of suicide attempt, overdose, and psychotic depression on Prozac compared to trazodone, as well as in regard to hostility and intentional injury. The drug company should have made these documents available to the public and the medical profession.

(7) Lilly probably never published the 38% figure for activation on Prozac. With certainty based on depositions by company executives, the company never published that many of the subjects were given addictive sedatives such as Valium against the rules for these studies as approved by the FDA. The sedatives temporarily suppressed some of the

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<sup>2</sup> Judge John W. Potter, 1997, p. 3.

activation symptoms in many patients. In addition, Lilly didn't include the full range of activation in its calculations, leaving out, for example, mania and hypomania.

(8) Psychiatrist Martin Teicher in USA Today on January 6, 2005 is quoted as saying that he never saw the documents. Furthermore, Dr. Teicher says he was told by Eli Lilly that there was no data confirming his own studies of Prozac-induced suicidality. Lilly has always said there was no such data in existence—misleading the FDA, the profession, and the public.

(9) Eli Lilly never sent the FDA the documents that the BMJ recently sent to Congressman Hinchey and the FDA. Richard Kapit, M.D. was the chief medical officer in charge of evaluating Prozac for the FDA during the drug approval process. The drug company completed the July 1985 suicide attempt evaluation of the clinical trials while Kapit was reviewing all drug company communications concerning Prozac's adverse effects. Breggin has reviewed the Prozac New Drug Application (NDA) including Kapit's internal memoranda as well as numerous depositions of Eli Lilly executives concerning the various documents. There is no evidence that Kapit or the FDA was made aware of the suicide attempt evaluation or any of the later documents. The Activation and Sedation study was completed after the drug was approved. It confirmed many of Kapit's stated concerns about Prozac's stimulation profile with the risk of worsening depression. It, too, was never sent to the FDA.<sup>3</sup> Of course, the drug company never sent "smoking gun" Bouchy memos to the FDA, nor did the drug company inform the FDA that it was recoding reported suicides and suicide attempts in order to disguise them as less serious adverse events.

(10) Lilly had completed and possessed all of the documents at the 1991 FDA PDAC hearing whose purpose was to evaluate the risk of antidepressant-induced suicidality. The only item produced from among all the documents was a single graph about hostility and intentional injury from the FDA's spontaneous reporting system. It was flashed on the screen by the FDA representative, never discussed, and then went missing at the FDA. Breggin tried to obtain that document before and after the Wesbecker case, and was finally told by letter from the FDA that they couldn't find it. In addition, and very important, while the FDA did show the hostility and intentional injury graph at the 1991 PDAC meeting, the agency did not show the dramatic graphs and tables concerning Prozac-induced suicide attempt, overdose and psychotic depression. Eli Lilly did not produce any information concerning these graphs at the hearings.

(11) Lilly continued to hide the documents and the data at the 2004 FDA hearings on pediatric suicidality caused by antidepressants. At the hearings Tom Laughren of the FDA said that he knew of no data linking SSRIs to suicide or hostility. Breggin openly contradicted Laughren during his presentation at the second hearing and told him that suicide data did exist in regard Prozac. The FDA continued to act unaware of the existence of any such documents in 2004 and did not ask Breggin any details about them.

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<sup>3</sup> Kapit's memos are described Breggin, P. and Breggin G. (1994), Talking Back to Prozac, and in Breggin, P. (1997), Brain-Disabling Treatments in Psychiatry.

(12) Lilly has secretly settled every one of several cases in which Breggin has been involved, sealing all of the documents.

### **III. Conclusions**

Eli Lilly never provided these important documents or any equivalent of them to the FDA, to other medical authorities or to professional publications in the interest of public health. Eli Lilly fought to keep them from surfacing, and when forced by litigation to offer them as discovery, the drug company settled cases and sealed the documents in order to avoid the documents becoming public. In the only case in which the documents were discussed in open court, the Wesbecker case, the Activation Documents and the Suicide Studies were not made into exhibits or entered into evidence. However, Breggin was allowed to testify about all of these documents. His testimony can be found on his website.

Eli Lilly's efforts to hide the documents have been so successful that plaintiff's lawyers typically have had little or no awareness of their existence. This has been greatly to the advantage of the drug company in settling cases to its satisfaction.

In conclusion, the Activation and Sedation Study, the Suicide Analysis from the clinical trials, and the Bouchy memos were never given to the FDA by Eli Lilly and Company. The FDA at one time possessed the graphs and tables concerning increased reports of "Suicide Attempts, Intentional Overdoses and Psychotic Depression" and "Hostility and Intentional Injury" but later the FDA could no longer locate them. Eli Lilly continued to hide all of these documents without releasing them to any government agency or medical authority, and without publishing them or even acknowledging their existence.

Until the release of these documents by the BMJ, Eli Lilly succeeded for many years in keeping each of these documents from surfacing. Despite their great public health importance, until now these documents have been largely unknown to the FDA, the legal profession, the medical and scientific community, and the public.

### **Background Materials:**

- (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.
- (2) Breggin, P., [Brain-Disabling Treatments in Psychiatry](#) (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." [International Journal of Risk and Safety in Medicine](#), 16: 31-49, 2003/2004. The Lilly documents are discussed in this peer-reviewed journal article. [Available on www.breggin.com](http://www.breggin.com).