

December 1, 2006

To: Psychopharmacologic Drugs Advisory Committee (PDAC) members
For: December 13, 2006 PDAC Regarding the Results of FDA's Ongoing meta-analysis of suicidality data from adult antidepressant trials

**Written Comments
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My name is Karen Barth Menzies. I am an attorney with the national law firm Baum Hedlund. For the past decade and a half (since 1990), my firm has represented more than 100 individuals across the country in suicide and suicide attempt cases involving SSRI antidepressants, including Paxil, Zoloft and Prozac.

Through our litigation, we have obtained internal company documents to which no one else has access, not even the FDA. Almost all of these documents are labeled confidential by the drug companies. Generally speaking, the only time these documents become publicly available is when a case goes to trial (only 3 have gone to trial). Nevertheless, short of trial, we have fought the companies to get the documents out from under confidentiality seal by seeking court orders to release the documents or by getting the companies to concede that the documents should never have been designated as confidential to begin with. As a result, a number of documents are now available to the public (although too many remain hidden and secret).

**Internal Documents Show that German Regulators Would Not Approve Prozac
Without Stronger Suicide Warning 20 Years Ago**

All of the Documents referenced in this submission can be found at:
<http://www.baumhedlundlaw.com/kbmfda.html>.

According to documents obtained in litigation, as early as 1984, German regulators had expressed concerns about Prozac and an increased risk of suicidality:

May 25, 1984 internal memorandum from Eli Lilly and Company ("Lilly," the maker of Prozac) regarding Lilly's efforts to obtain registration of Prozac in Germany: "During the treatment with the preparation [fluoxetine] 16 suicide attempts were made, 2 of these with success. As patients with a risk of suicide were excluded from the studies, it is probable that this high proportion can be attributed to an action of the preparation in the sense (sic) of an deterioration of the clinical condition, which reached its lowest point." (<http://www.baumhedlundlaw.com/01.pdf>)

June 26, 1984, item # 10: "The BGA [German equivalent of FDA] suspects fluoxetine [Prozac] to be a stimulating/activating drug (side-effect profile, suicides, suicide attempts)." Item # 14 states: "This is a very serious issue in the opinion of the BGA. It might well be that we will have to recommend concomitant tranquilizer intake for the first 2 or 3 weeks in the package literature." (<http://www.baumhedlundlaw.com/02.pdf>)

January 29, 1985 states: “Two major concerns seem to be the reason that the registration was not accepted,” “efficacy questioned” and “suicidal risk.”
(<http://www.baumhedlundlaw.com/03.pdf>)

February 26, 1985 states: “The use of the preparations seems objectionable, as the increase in agitating effect occurs earlier than the mood elevating effect and therefore an increased risk of suicide exists.” (<http://www.baumhedlundlaw.com/04.pdf>)

April 1, 1986 memorandum, under a discussion of safety issues: “Still not resolved is the fact that suicide attempts have been observed more frequently on fluoxetine as compared to imipramine According to the today's knowledge [fluoxetine's “favourable” side effect spectrum] is negatively affected by the increased suicidal risk.”
(<http://www.baumhedlundlaw.com/05.pdf>)

August 30, 1989, Additional Feedback Regarding the Fluoxetine Review by Commission A (an expert working/consultant group to BGA), Item 3 states: “The counterindication because of acute suicidality should become a warning whereby the physicians should be advised that in the absence of sedation, the risk of higher suicidality should be taken into account.”
(<http://www.baumhedlundlaw.com/06.pdf>)

FDA Safety Officer Recognized Dangerous Side Effect Profile in 1985:

According to FDA's March 1985 Safety Review of Prozac, conducted by Dr. Richard Kapit: “It is fluoxetine's particular profile of side effects which may perhaps, in the future, give rise to the greatest clinical liabilities in the use of this medication to treat depression.”
(<http://www.baumhedlundlaw.com/07.pdf>)

Under “Catastrophic and Serious Events,” Dr. Kapit noted: “... 52 cases were [] subjected to review of case reports on microfiche. Certain additional adverse events, **not reported by the Company**, which were revealed on microfiche, are also included in this tabulation. In most cases, these adverse events involved the onset of an **unreported psychotic episode.**”
(<http://www.baumhedlundlaw.com/08.pdf>)

Dr. Kapit explained: “[F]luoxetine's profile of adverse effects more closely resembles that of a stimulant drug than one that causes sedation and gain of weight,” therefore, “fluoxetine treatment might, at least temporarily, make their illness worse.”
(<http://www.baumhedlundlaw.com/09.pdf>)

1991 – FDA's Failure to Take Action

Notwithstanding the German government's recognition in the mid-1980's of an increased risk of suicidality and Dr. Kapit's concern over Prozac's side effect profile, the public concern over the risk of antidepressant-induced suicidality did not emerge until 1990 when two prominent Harvard psychiatrists, Drs. Martin Teicher and Jonathan Cole, published a study entitled “Emergence of Intense Suicidal Preoccupation During Fluoxetine [Prozac] Treatment.” From their personal observations of patients taking Prozac, Drs. Teicher and Cole, after first noting that four of the six

patients referenced in their study experienced akathisia (a condition marked by profound inner restlessness and agitation), found that “persistent, obsessive, and violent suicidal thoughts emerged in a small minority of patients treated with fluoxetine.” (<http://www.baumhedlundlaw.com/10.pdf>)

The FDA thereafter assembled a group of psychiatrists to serve on its PDAC to discuss the issue. The advisory committee meeting took place on September 20, 1991.

Lilly assigned Dr. Gary Tollefson to testify at the September 1991 PDAC. According to his November 16, 1994 testimony in the Prozac case, *Fentress v. Shea et al.*, Case No. 90-CI-06033, he did not disclose to the FDA the fact that the issue had been raised by the German government in 1984/1985. Dr. Tollefson testified:

Q. . . . Doctor [Tollefson], to back up a little bit, earlier you said . . . that the first time the issue of using Prozac and the incidence of suicide was raised [was] in 1990 by Doctor Teicher's article; correct?

A. It was the first time that I was aware of the issue having arisen at that time.

Q. Okay. So let's make sure we're clear on this. That issue was raised by the German government back in 1984; correct?

A. I have heard that indication, yes.

* * *

Q. Were you aware in 1991, when you testified before the PDAC, that Lilly had in fact hired experts back in 1985 and 1986 to look at [the suicide] issue with regards to the German government?

A. I had heard that there were some individuals that have consulted previously with Lilly on those issues but did not know specifically whether it was related to the BGA or the issue in general.

Q. Okay. Did you tell the PDAC in 1991, that Lilly had previously - and I'm talking about prior to Doctor Teicher raising the issue, that Lilly had previously hired experts to look at the issue of increased suicide and the use of Prozac?

A. I think as part of the presentation it was made clear that a very thorough and comprehensive analysis of the worldwide data on suicide and Prozac had been made.

* * *

Q. Let's try it one more time. Specifically, did you tell the PDAC that prior to 1990, when the German government raised this issue, that Lilly hired experts to investigate the issue of increased suicide and the use of Prozac, yes or no?

A. That was not a question I was asked by the PDAC, so I did not answer that question.

Q. Did you volunteer it?

A. No.

* * *

Q. Did you inform the committee that there was a package insert in use in Germany, on the day of the advisory committee, that recommended the use of sedatives in people who were suicidal or agitated on Prozac? . . .

A. That was not one of the points of discussion.

Q. The answer is you didn't; right?

A. Again, I did not feel there would be any reason.

(Testimony of Dr. Gary Tollefson, transcript, p. 111:9-25; 114:10-115:15; 118:2-119:2:
<http://www.baumhedlundlaw.com/11.pdf>)

FDA Officials Treat 1991 PDAC and Suicide Risk as a “Public Relations Problem”

Through documents obtained in litigation, we learned that the FDA never took this issue seriously. According to a GlaxoSmithKline (GSK) memorandum dated October 3, 1990, the FDA believed the public controversy that had erupted concerning the potential for antidepressants to increase the risk of suicide in adults was, to the FDA, not “a real issue, but rather [] a public relations problem.” The FDA’s Dr. Martin Brecher indicated to GSK that the FDA “does not think it is an issue, but it needs to be addressed.” (<http://www.baumhedlundlaw.com/12.pdf>)

1991 PDAC Conclusion: “More research and data is needed”

Although the committee members ultimately voted that there was insufficient data to conclude that Prozac caused suicide (the question posed was: “Is there credible evidence to support a conclusion that antidepressant drugs cause the emergence and/or intensification of suicidality and/or other violent behaviors?”), the FDA stated that it did “not dismiss the possibility that antidepressants in general or fluoxetine in particular may have the capacity to cause untoward injurious behaviors and acts, and/or to intensify them.” The FDA concluded that “more research is needed” and “asked [Lilly] to develop plans to conduct new studies, including clinical trials and epidemiological studies, studies that could provide more direct answers to the questions that have been raised” in the advisory committee meeting. (September 1991 PDAC Transcript at 128:18-24:
<http://www.baumhedlundlaw.com/13.pdf>.)

The FDA advisory committee only saw data from the Prozac clinical trials. Had the committee seen the data from the Paxil clinical trials, things might have ended quite differently. After the FDA asked GSK to submit an analysis of its clinical trial data in order to respond to the public’s concerns about the risk of suicidality, GSK responded by inappropriately adding suicide events that occurred in the placebo run-in/wash-out period, thus masking Paxil’s suicidality risk. When the placebo run-in/wash-outs are removed, Paxil users were over 8 times more likely to have engaged in suicidal behavior than those on placebo. At the time, had GSK properly reported this to FDA and had FDA actually noticed the actual Paxil suicidality risk, this would have had a devastating impact on Paxil’s capacity to compete with Prozac, an SSRI with an already established market, and, under proper FDA supervision, may have even impacted Paxil’s ability to have obtained FDA approval. Moreover, it would likely have had a substantial impact upon the PDAC’s conclusions and the whole history of the hidden risk of SSRI-induced suicidality.

Post 1991 – None of the Companies Conducted Follow-up Research Nor Did FDA Push Them to Do So

Despite the PDAC's mandate that further research be conducted, no such studies were ever conducted by Lilly or any other SSRI producing company.

In fact, Lilly proposed a protocol for a “rechallenge” study of patients who developed suicidal ideation while under Prozac treatment, but never performed the study. In addition, a more sensitive scale for detecting treatment emergent suicidality was developed that could have been utilized in ongoing and future clinical trials, however, the scale was never implemented.

According to Lilly's answers to Interrogatories submitted under oath in the lawsuit *Biffle v. Eli Lilly*: “Discussions were had between Lilly and the FDA regarding possible data analyses or clinical trial designs which would test whether the Teicher assertions are in fact real. The FDA did not request or require any action from Lilly nor suggest a particular analytical of study approach. *The discussions and question as to whether additional studies be done were mooted by the findings of the FDA Psychopharmacological Drug Advisory Committee on September 20, 1991. No additional studies were conducted.*” (<http://www.baumhedlundlaw.com/14.pdf>)

This statement is demonstrably false. According to a letter the FDA sent to Public Citizen in June 1992: “There was a consensus [amongst the PDAC above] that *more research is needed* to further explore the relationship between suicidality and the use of not only Prozac, but other antidepressants as well.” The FDA further stated that it would “continue our careful evaluation of data in our spontaneous reporting system and *encourage additional research* on this matter.” (<http://www.baumhedlundlaw.com/15.pdf>)

None of the antidepressant manufacturers at the time nor since then, has conducted a single safety oriented study to examine the risk nor have they utilized more sensitive measures to detect treatment-emergent suicidality.

Lilly's Analysis of Prozac Clinical Trial Data Criticized

Lilly published its meta-analysis of Prozac clinical trial data in 1991, which meta-analysis was hotly criticized. As one scientist explained it, “the term meta-analysis sounds rather grand, but it is worth no more than the quality of the original data collection... What was needed was a critical assessment, independent of the manufacturers, that included assessment of the quality of data collection—and not Eli Lilly's employees deciding which clinical comments should be ‘eliminated.’” Oswald, “Fluoxetine and suicide” *BMJ* 1991 Oct 26;303(6809):1058-9. He concluded: “A negative result of research, a failure to find something, can arise from lack of sensitive research techniques.” *Id.*

According to an internal Pfizer memorandum obtained in litigation and written by Pfizer's top scientist at the time: “I do not think fluoxetine are ‘out of the woods’ as regards their association with violence/ suicidality. The recent meta-analysis of controlled clinical trials (Beasley et al, *BMJ* 303: 685-692, 1991) was initially followed by favorable comment but skeptical voices remain. A recent re-analysis of the data from this study using Monte-Carlo simulations

demonstrates the conclusions of the Beasley paper to be invalid as this original meta-analysis had low power (LiWan PoA. Pharmacoepidemiology and Drug Safety 2: 78-84, 1994).” January 20, 1994 memo from Roger Lane to Giller regarding Use of Zoloft in Impulsive/ Aggressive Behaviour. (<http://www.baumhedlundlaw.com/16.pdf>)

FDA epidemiologist, Dr. David Graham, also criticized Lilly’s meta-analysis, which had been submitted to FDA in September 1990. In a document obtained from the FDA through the Freedom of Information Act, Dr. Graham stated:

Suicidality. The firm [Lilly] reviewed data from NDA studies, prefacing it with the acknowledgment that these trials were not designed for the prospective evaluation of suicidality. In these trials patients with current suicidal ideation were excluded. Suicidal ideation was studied in two ways. The first involved analysis of clinical comments ascertained through non-probing, open-ended questions during the trial. Also, at the beginning and end of the study, patients completed a self-administered questionnaire, the Hamilton Rating Scale for Depression, which included one question on suicide. This question, referred to as HAMD-3, rated suicidal ideation on an ordinal scale from 0 (absent) to 4 (severe ideation, usually with an attempt). The capacity of these trials to identify and describe the quality and intensity of suicidality was low.

Dr. Graham made a number of other important points:

a. Dr. Graham criticized Lilly’s “meta-analysis,” which was being touted by Lilly as showing that there was no relationship between Prozac and suicidality. (“In the meta-analysis of suicidality from the IND trials, 76 fluoxetine cases were excluded from analysis because the patients were in studies or other trials lacking comparative controls.”) (Graham memo p. 4: <http://www.baumhedlundlaw.com/17.pdf>);

b. Dr. Graham questioned Lilly's reliance on an abstract by Fava & Rosenbaum which Lilly asserted showed "no statistically significant differences among rates of treatment-emergent suicidal ideation associated with five classes of antidepressant therapy." (When Dr. Graham re-analyzed Fava & Rosenbaum's data he found that "Treatment-emergent suicidality was more frequent among 'fluoxetine alone' than 'tricyclics with or without lithium' patients. The relative risk of suicidality was 3.3. (95% CL 0.9, 12.2), p-0.07.") (Graham memo p. 4);

c. Dr. Graham validated the report by Teicher, et al., which first discussed the relationship between Prozac and suicide ("Interestingly, the proportion of patients with treatment-emergent suicidality on fluoxetine in this study was similar to that reported by Teicher et al.") (p. 6).

d. In conclusion, Dr. Graham stated: “The firm’s analysis of suicidality does not resolve the issue. The firm acknowledged that its clinical trials were not designed to study this and specificity of data to be gleaned from these trials to address suicidality were poor. . . . Because of apparent largescale underreporting, the firm’s analysis cannot be considered as proving that fluoxetine and violent behavior are unrelated.”

Clinical Trials are not designed to adequately test for side effect of suicidality

The hypothesis of whether antidepressants cause suicidality has *never* been prospectively studied. Clinical trials are useful to prove that a drug has an intended effect, however, they were not designed to determine questions such as whether a drug is causing suicidality.

1. Clinical trial data is not a good measure to test rare events. Suicidality, particularly completed suicides, are rare events. Patients who are suicidal are excluded from most clinical trials, and a significant percentage of patients quit clinical trials due to side effects.

- Epidemiologists Gunnell and Ashby (1995 *BMJ* article) wrote:

“Suicide is rare, even among people with depression. [Cite omitted.] Thus, most clinical trials have insufficient power to provide clear evidence on the effect of antidepressants on suicide.”

- As the editor of the *New England Journal of Medicine* thoughtfully explained:

First “a drug is approved because it is more effective than placebo.” Then, “worries emerge about its safety.” However, “few or no adequately powered controlled trials [conducted by drug companies] are conducted to address these issues.” Thus, “The health care system has a hard time performing drug safety analyses, in large part because it relies on the pharmaceutical industry to conduct most research on the risks and benefits of medications. It is naive to expect companies to voluntarily fund studies that could sink lucrative products” and further complicating matters is the fact that “the FDA lacks regulatory clout to require them.” (*N Engl J Med.* 2006 Nov 23;355(21):2169-71: <http://www.baumhedlundlaw.com/18.pdf>)

- Further, in reviewing the relationship between SSRIs and pediatric suicidality, the FDA explained: “Pooling of trials is often performed when investigating infrequently occurring adverse events observed in drug development programs as it provides a more robust point estimate of the risk associated with drug use. *Single trials are almost invariably insufficiently powered for detecting signals for uncommon events.*” (<http://www.baumhedlundlaw.com/19.pdf>, p. 23, emphasis added.)

Despite the unlikelihood that a statistically significant increased risk will be found from clinical trials conducted by drug companies to obtain FDA approval, meta-analyses of both child/adolescent and adult clinical trials have revealed a risk.

- Dr. Thomas Newman, an epidemiologist from the University of San Francisco and an advisor to the FDA on the issue of child/adolescent suicidality (following recommendations that antidepressants carry black box warnings) noted that, the fact that higher rates of suicidality in those taking antidepressants have emerged from the clinical trials is “striking” and “such a dramatic result would be expected to occur by chance only 1 time in 20,000.”

- Dr. Newman observed that “some FDA staff and committee members expressed reservations about the data used for this analysis,” but as he explained, “these concerns only made the results more compelling.” He further stated: “The fact that an association emerged from the meta-analysis ... for an outcome that the sponsors of the trials were not looking for, and presumably did not wish to find, was quite convincing.” (<http://www.baumhedlundlaw.com/20.pdf>)

The fact that a risk has been detected in clinical trials not intended to answer this question for an event that is rare, even in depressed patients, makes the evidence even stronger.

2. HAMD an insensitive measure of treatment-emergent suicidality

Rather than legitimately studying the link between their drugs and suicidality, SSRI manufacturers have conducted analyses of their clinical trial databases using a scale called the “Hamilton Depression Scale” (HAMD), a scale used to assess changes in the degree of depression of patients enrolled in the clinical trials. The HAMD contains one question concerning suicidality. It is an insensitive measure of treatment-emergent suicidality. Nevertheless, these analyses, inaccurately described as “thorough,” have been used by the manufacturers to claim their drugs have been “exonerated” against claims of increased suicidality.

- Drs. Healy and Creaney criticized Lilly’s analysis in 1991 and Lilly’s use of HAMD Item 3 to analyze the risk (1991 *British Medical Journal* article):

Lilly’s “analysis of whether there is an association between fluoxetine and suicidality does not entirely settle the question raised by Teicher/Cole of whether treatment with fluoxetine may in certain instances lead to suicidal ideation.” There were several reasons for this, the first being that “item 3 of the Hamilton scale for depression, ratings on which provide the data for the analysis, is an insensitive measure of suicidality ... the capacity of these trials to identify and describe the quality and intensity of suicidality was low.”

- Senior FDA epidemiologist, Dr. David Graham was likewise skeptical of Lilly’s use of the HAMD Item 3 measure:

Lilly’s “analysis of suicidality does not resolve the issue.” (<http://www.baumhedlundlaw.com/17.pdf>, p.4.)

3. FDA finally acknowledge the inadequacy of its review of SSRI suicide data

Unfortunately, it took FDA officials over a decade to figure this out. Senior FDA officials recently acknowledged at the Congressional hearings and the Advisory Committee hearings in 2004 that its analysis of the SSRI-induced suicidality was inadequate.

- In testimony before Congress resulting from investigations of the FDA’s failure to protect consumers related to the antidepressant suicidality issue, the FDA’s Dr. Robert Temple defended the agency’s failure, stating that although the FDA “had been systematically looking at the adult data for almost that entire decade” and had

“not seen a signal in that data,” Dr. Temple admitted that the FDA’s analyses could have been far “better, more structured, [and] more careful, ... but we didn’t know to do that.” (<http://www.baumhedlundlaw.com/21.pdf>, p. 100.)

- At the February 2, 2004, FDA advisory committee meeting concerning the risk of suicidality in children and adolescents taking antidepressants, the FDA’s Dr. Thomas Laughren similarly explained: “Just one follow up on a suggestion that has come up from several committee members now about looking at items from the rating scales. That was actually done here, and it turned out not to be very helpful. Now, this was a similar analysis that had been done with the adult data years ago. ... ” He explained that this method “did not detect a signal in these trials ... ” and admitted that the method was “was not particularly productive.” (<http://www.baumhedlundlaw.com/22.pdf>, pp. 342-343.)

GSK’s May 2006 Analysis of Paxil Clinical Trials Confirms Risk in Adults

For its meta-analysis of suicidality data from the adult clinical trials, the FDA asked companies to submit data only from short term depression studies up to 17 weeks, which had at least 30 patients in the study. GSK decided to do its own blinded analysis of its adult clinical trial data. The results of the new analysis showed: “In adults with MDD (all ages), there is a statistically significant increase in the frequency of suicidal behavior in patients treated with paroxetine compared with placebo.” (<http://www.baumhedlundlaw.com/23.pdf>)

The masking of this risk in previous analyses was the result of a contamination of the dataset from inappropriately included anomalous studies. Once these studies were excluded due to FDA’s criteria, the increased risk of suicidality in adult patients taking Paxil, which had been evident from GSK’s initial submission, reappeared. The odds ratio is 6.7.

As a result of GSK’s recent analysis, GSK strengthened Paxil’s label to include this new information and sent a “Dear Doctor” letter to every doctor in the United States including this information. *Id.*

The Question of Efficacy

Doctors must weigh the benefits of drug treatment versus the risks. In order to do a proper risk benefit analysis, a doctor must be aware of the degree of effectiveness of the drug – not just drug company hype. Is the drug extremely effective or only marginally effective? Doctors know the drug was approved by the FDA, but do they know the FDA’s standards for approving a drug as effective?

In an analysis of efficacy data submitted to the FDA between 1987 and 1999 for six of the most popular selective serotonin reuptake inhibitor (SSRI) antidepressants, 75 to 80% of the response to medication was duplicated in placebo groups. (Kirsch and Moore, "The Emperor’s New Drugs: An Analysis of Antidepressant Medication Data Submitted to the U.S. Food and Drug Administration," *Prevention & Treatment*, Volume 5, Article 23, July 15, 2002.) These data were the basis on which the medications were approved by the FDA. The researchers explained that the

“small difference between the drug response and the placebo response has been a ‘dirty little secret’ known to researchers who conduct clinical trials, FDA reviewers, and a small group of critics who analyzed the published data ...” Kirsch, Moore et al., "Antidepressants and Placebos: Secrets, Revelations, and Unanswered Questions," *Prevention & Treatment*, Volume 5, Article 33, posted July 15, 2002 (<http://www.baumhedlundlaw.com/24.pdf>), Moncrieff and Kirsch, "Efficacy of antidepressants in adults" *BMJ* July 2005 (<http://www.baumhedlundlaw.com/25.pdf>).

FDA approval of these drugs implies that the data were strong enough and reliable enough to warrant approval, however, as one FDA memorandum written by Dr. Paul Leber illustrates, the FDA’s standards for approving antidepressants as effective are not robust: “Approval [of the antidepressant] may ... come under attack by constituencies that do not believe the agency is as demanding as it ought to be in regard to its standards for establishing the efficacy of antidepressant drug products.” (<http://www.baumhedlundlaw.com/26.pdf>)

No Scientifically Reliable Evidence that Declining Suicide Rates are the Result of Increased Prescriptions of Antidepressants

On the issue of national suicide rates going down and, in particular, on the possible impact of antidepressants on these rates, as one renowned expert has noted: “This argument is like saying that, because there has been an increase in storks seen recently and a coincidental increase in births, babies are therefore brought by storks.” (Declaration of Dr. David Healy, *Tucker v. GSK.*)

In fact, according to Gunnell et al.¹, "Antidepressants and suicide: what is the balance of benefit and harm," *British Medical Journal (BMJ)*, 2004; 329:34-38 (3 July):

Surprisingly, direct evidence that antidepressants prevent suicide is hard to find. ... In the most comprehensive synthesis of data from randomised trials, Khan and colleagues found no evidence of a beneficial effect of antidepressants on suicide.

Gunnell, citing Khan A, Khan S, Kolts R, Brown WA. “Suicide rates in clinical trials of SSRIs, other antidepressants, and placebo: analysis of FDA reports,” *Am J Psychiatry* 2003;160: 790-2

The authors also pointed out that “Suicide is rare, even among people with depression. [Cite omitted.] Thus, most clinical trials have insufficient power to provide clear evidence on the effect of antidepressants on suicide.” Gunnell *citing* Jick SS, Dean AD, Jick H. Antidepressants and suicide. *BMJ* 1995;310: 215-8.

According to a study by Herman Van Praag published recently in *World Journal of Biological Psychiatry* titled “A Stubborn Behaviour: the Failure of Antidepressants to Reduce Suicide Rates,” despite the increased use of antidepressants “completed suicide has remained quite stable” and “suicide attempts even seem[] to have increased.”

¹ David Gunnell is professor of epidemiology, University of Bristol and Deborah Ashby is professor of medical statistics, Queen Mary’s School of Medicine and Dentistry

Conclusion

For over a decade and a half, SSRI manufacturers have enjoyed enormous financial benefits from the flawed results of their defective analyses and their manipulations of the clinical trial data. They have been further shielded by their own failure to legitimately study and examine this serious risk. Instead, they have relied on studies that were not designed to detect a risk and conducted illegitimate analyses from them. Like an ostrich, they stuck their heads in the sand and pretended that no such risk could possibly exist, so why look? They have blamed patients, arguing that it's "the disease, not the drug." The FDA, likewise, has been derelict in its duties in protecting the public health on this issue. While it appears that the FDA has finally taken the issue more seriously, it is 20 years and thousands of lives too late. Through my representation of the more than 100 families I referenced at the beginning of this submission, families who have lost loved ones to suicide or who have attempted suicide themselves while under the influence of an antidepressant, I have been touched by a tremendous sense of duty to prevent this terrible tragedy from continuing to happen to others. I am moved and motivated by my clients to seek out and expose the truth so their loved ones' lives will not be in vain.

Should these companies be further rewarded for placing profits over human lives? I don't think so. I urge the committee to be very thoughtful in considering this issue.

Sincerely,

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