

In Ireland since the introduction of the SSRIs and the overprescription of them to this day. The suicide rate have **increased** at a similar rate than the prescription of these drugs.

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SSRI Experts Head to Washington to Testify Before FDA Panel

By **Evelyn Pringle**

On December 13, 2006, the FDA's Psychopharmacologic Drugs Advisory Committee will hold a public hearing to review the suicidality data from the adult selective serotonin reuptake inhibitor (SSRI) studies.

And, for what seems like the umpteenth time, SSRI experts from all over the US, and as far away as the UK, will travel to Washington to once again testify at yet another hearing on the suicide risks associated with
Evelyn Pringle these drugs.

The committee is expected to vote on whether the risk of SSRI-induced suicidality in adults should be included in a Black Box warning on all SSRI labels, including Paxil, Prozac, Zoloft, Lexapro, and Celexa.

The FDA should begin the hearing by announcing that suicide rates for adults have not declined at all in the US even with the

massive wide-spread use of SSRIs. According to a Federal study, by researchers from Harvard Medical School and elsewhere, in the June 2005, Journal of the American Medical Association, despite a dramatic increase in treatment with antidepressants in 2001-2003, when compared to 1990-1992, the rates of suicidal ideation, gestures and attempts among adults have remained basically unchanged.

There is probably no legal expert in the US more qualified to testify about SSRIs than Baum Hedlund attorney, Karen Barth-Menzies, and she will be at the hearing with bells on. Over the past 10 years, she has represented thousands of clients against SSRI makers.

By now, the FDA knows that Ms Menzies makes no secret of the fact that she is outraged about the over-prescribing of these powerful and dangerous drugs to all age groups for nothing more than everyday problems.

This will be Ms Menzies' fourth time up to bat. She has already testified three times at government hearings. She first spoke at an FDA Psychopharmacologic Drugs and Pediatric Advisory Committee hearing in February 2004, about the increased risk of suicide in children and adolescents taking SSRIs.

At that particular hearing, the famous SSRI litigator concluded her testimony by telling the panel: "Put me out of business for the right reasons. Warn about these drugs."

Many of Baum Hedlund's clients who have suffered tragedies caused by SSRIs will be also be attending the hearing and some will be speaking. However, a number of clients who wanted to testify were not selected by the FDA's new "lottery" system, and will not be permitted to speak. But Ms Menzies says she plans to speak on their behalf.

She has first-hand knowledge of how the drug companies hid the evidence about the suicide risks. The documents that have been unearthed in litigation reveal that the risk was known in

the mid-1980's before the first SSRI, Prozac, was approved for use in the US.

Because of Baum Hedlund's work in the Prozac litigation, Ms Menzies has the ability to provide the committee with the historical background on SSRIs, including internal company documents that show how and why the SSRI suicide risk with adults was obfuscated fifteen years ago during the first FDA advisory committee hearings on the suicide issue.

She will explain exactly how the clinical trial data was manipulated by SSRI makers to skew the statistical analyses of suicidality. "Civil lawsuits," she says, "have uncovered internal company documents to which not even the FDA has access."

And she maintain that the drug makers have purposely failed to conduct studies on the risk of suicidality because they already knew such trials would produce negative results.

In August 2004, Ms Menzies testified before the California State Senate and called for better patient informed consent about the risks associated with SSRIs.

Next, she testified at the September 2004, FDA Advisory Committee's follow-up hearings and discussed the lack of efficacy in SSRI treatment of children, as documented in pediatric clinical trials that had surfaced during litigation.

In between the February and September 2004 hearings, Ms Menzies met with members of Congress to discuss SSRI related suicidality and the FDA's failure to alert the public about the dangers of SSRIs, and provided documentary evidence to show that the risks posed were real.

She also provided information to investigators in two separate Congressional investigations that resulted in two hearings in 2004, at which drug company executives and FDA officials were interrogated and chastised by members of Congress.

In addition to Ms Menzies, one of the world's most highly regarded SSRI experts, [Dr David Healy](#), a professor at North Wales Department of Psychological Medicine, at Cardiff University, will be flying in from the UK to testify at the hearing. He too will give a repeat performance.

Dr Healy has authored 12 books including, *Let Them Eat Prozac*, *The Antidepressant Era*, and *The Creation of Psychopharmacology*, and is known to be outspoken when he believes it is necessary. During his testimony at this hearing, Dr Healy says he plans to draw attention to the manipulation of the clinical trial data on SSRIs.

For over a decade, he has been trying to raise awareness about the link between SSRIs and suicide. Back in August 1991, Dr Healy authored the paper, "Antidepressant Induced Suicidal Ideation," in which he said that the cases of two patient "suggest that the emergence of suicidal ideation on antidepressants cannot always be attributed to a lifting of psychomotor retardation but rather that the ideas may in some instances be produced by antidepressants."

Three years later in 1994, he authored the paper, "The Fluoxetine and Suicide Controversy," and stated, "In the opinion of this author, the volume of case reports and other studies is sufficient to demonstrate that antidepressants and antipsychotics may induce suicidal ideation in certain individuals under certain conditions."

After the February 2004 advisory committee hearings, Dr Healy analyzed the data from the pediatric SSRI trials on suicidality and hostility, including those kept hidden for years, and sent his analysis to the FDA on February 19, 2004.

To distinguish the difference between suicide possibly caused by SSRIs verses suicide caused by an underlying illness of depression, Dr Healy broke down the studies into a group of children being treated for depression and a group of anxious

children who were being treated for obsessive compulsive disorder or social phobia.

From a pool of 931 depressed patients taking SSRIs versus 811 depressed patients taking placebo, Dr Healy determined that there were 52 suicidal acts by patients on SSRI versus 18 in the placebo group.

In a pool of 638 anxious patients taking SSRIs versus 562 anxious patients taking a placebo, there were 10 suicidal acts in the SSRI group versus 1 in the placebo group.

When these data sets were combined, in the 1569 patients on SSRIs there were 62 episodes of suicidality versus only 19 episodes in 1373 patients on a placebo.

This analysis clearly shows that SSRIs can cause some children who were not depressed to begin with to become suicidal.

Dr Healy believes the FDA should do more about the industry's practice of paying medical professionals to publish fraudulent research papers ghostwritten by PR firms. "While it is not FDA's brief to regulate the academic literature," he states, "the possibilities of a close to fraudulent representation of data and of extensive ghostwriting does set up an argument that these apparently scientific articles are in fact infomercials rather than the real thing."

"If these articles are essentially advertisements," Dr Healy says, "it is much less clear that FDA can throw their hands up and plead an inability to do anything about the production of such materials."

Former Federal fraud investigator, [Allen Jones](#), will also be testifying at the hearing and he too has testified before about the over-promotion and marketing of psychiatric drugs.

"The pervasive manipulation of clinical trials, the non-reporting of negative trials and the cover-up of debilitating and deadly

side effects," Mr Jones says, "makes it impossible to prescribe, or take, these drugs with any level of meaningful informed consent."

"Doctors and patients alike," he states, "have been betrayed by the governmental entities and officials who are supposed to protect them."

During an investigation in Pennsylvania, Mr Jones learned all about Big Pharma's methods promoting the sale of psychiatric drugs by corrupting public officials and says, "conflicts of interest permeate the testing, approval and marketing of drugs in America."

"Academic researchers with industry ties," he explains, "put favorable spin on dubious clinical trial results and then the embellished results are presented to FDA Advisory Boards peopled with Pharma consultants, grantees and advisors."

"These results," he reports, "are further embellished in medical journals by still more academics on drug company payrolls."

From there, he says, this body of misleading research becomes institutionalized by "expert panels" in treatment guidelines generated by additional academics and researchers with financial ties to the industry.

As a fraud investigator, he discovered a hidden account in Pennsylvania where drug companies were funneling money to the state employees who were in charge of deciding which psychiatric drugs could be included in the treatment guidelines for the official list of drugs covered by public health plans like Medicaid and prescribed to people in all state institutions and programs.

According to Mr Jones, the employees "were given unrestricted educational grants that were deposited into an off-the-books account, unregistered, unmonitored, literally operated out of a drawer."

Mr Jones also found that the drug makers were paying these same state employees honorariums of up to \$2,000 to speak at industry events and giving them perks such as lavish meals and trips.

After the SSRIs and atypical antipsychotics were successfully added to the state formulary list, Mr Jones reports, Pennsylvania spent a combined total of \$139 million in 2003, for those 2 classes of drugs alone.

Last month, the former Pennsylvania Chief Pharmacist, identified as being on the take by Mr Jones during his investigation, was indicted on felony and misdemeanor conflicts of interest charges involving accepting money from drug companies while a state employee with great influence over the drugs that would be added to the state formularies to be prescribed to patients in Pennsylvania.

"I predict we will be seeing many more prosecutions of this type," Mr Jones says, "as the extent of drug company corruption of government officials becomes known."

Another prominent SSRI expert making a return visit to testify once again is [Dr Joe Glenmullen](#), a psychiatrist and clinical instructor in psychiatry at Harvard Medical School, and the author of the book, "Prozac Backlash," which describes his experiences of watching patients become suicidal while taking SSRIs.

He has testified previously about a specific side effect of SSRIs called akathisia, that he and many other experts say, can make some patients so agitated that they feel death would be a welcome relief.

"This side effect is so well established," Dr Glenmullen told a previous panel, "that it is clearly described with SSRIs in the Diagnostic and Statistical Manual, the DSM, the American Psychiatric Association's official diagnostic manual."

"If you look at the transcript of the FDA hearing on this very side effect 10 years ago," he stated, "you will see the FDA saying repeatedly we don't know what to do, we need more research."

"It is a tragedy," he added, "to be here 10 years later and hear the FDA saying the same thing."

"The industry's response to this side effect," he continued, "has been to blame the underlying psychiatric conditions of patients, to dismiss legitimate medical case reports as anecdotes, and to scare the media away from the subject, claiming that it would frighten patients away from treatment."

"Well, I prescribe SSRIs and I warn patients," he told the panel, "and they are not frightened away from treatment."

In conclusion, Dr Glenmullen clearly stated that the suicidality in SSRI patients was not caused by an underlying psychiatric condition, that it was caused by akathisia.

"Let's stop blaming the victims," he said, "and deal with this very real side effect."

Evelyn Pringle
evelyn-pringle@sbcglobal.net

Authors Bio: Evelyn Pringle is a columnist for OpEd News and investigative journalist focused on exposing corruption in government and corporate America.

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