

Doctors Ignore Black Box Warnings On SSRIs

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By **Evelyn Pringle**

Washington, DC: The FDA has issued numerous public health advisories and black box warnings over the past several years about the increased risk of suicidality associated with *selective serotonin reuptake inhibitor* antidepressants, but many doctors ignore them.

In October 2004, the FDA added a black box warning about an increased risk of suicidality in children and adolescents after a review of data showed a doubling of the risk of suicidality associated with the drugs.

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In December 2006, the FDA's Psychopharmacologic Drugs Advisory Committee held a public hearing to review the suicidality data on adults and recommended that the black box warning to be extended to young adults.

SSRIs sold in the US include Prozac, by Eli Lilly, Paxil, by GlaxoSmithKline, Zoloft, by Pfizer, and Celexa and Lexapro, by Forest Laboratories, along with some generic versions.

In the briefing material for the hearing, the FDA for the first time admitted that SSRIs also increase the risk of suicidality in patients over 18. In fact, the data presented showed the rate of suicidality in adults more than doubled from about 3 cases per thousand to seven.

As usual, proponents advocating for stronger warnings on SSRIs were up against a stacked deck at the hearing. During his testimony before the committee, former Federal fraud investigator, **Allen Jones**, identified numerous conflicts of interests among the panel.

He testified that doctors and patients alike have been betrayed by the governmental agencies that are supposed to protect them, and that, "the love affair between the pharmaceutical industry and our government institutions has to end."

This particular committee, he told the audience, included 3 people with financial ties to the industry who were granted waivers. One was granted to **Dr Andrew Leon**, Mr Jones said, even though he receives between \$10,001 and \$50,000 a year as a member of a data-monitoring board for an undisclosed company that sells antidepressants.

<Andrew Leon, Ph.D., Professor of Biostatistics in Psychiatry and Professor of Public Health, Weill Medical School of Cornell University, New York City. Receives between \$10,001 and \$50,001 per year as a member of a data monitoring board for a firm affected by policy decisions for antidepressant drugs. (<http://www.fda.gov/ohrms/dockets/ac/06/waivers/2006-4272w1-04-Leon-ack.pdf>; accessed 11/30/06) Owns stock in a competitor of Cephalon.

(http://www.fda.gov/ohrms/dockets/ac/06/waivers/2006-4212W1_02_Goodman_ACK.pdf); Consultant to Cyberonics, Inc., and Cortex Pharmaceuticals. Completed a manuscript and presentation for Forest Laboratories titled, "Are Two Antidepressant Mechanisms Better than One? Issues in Clinical Trial Design and Analysis." (Preliminary Report of the Task Force on SSRIs and Suicidal Behavior in Youth, American College of Neuropsychopharmacology, 1/21/04, p.16; on file with CSPI) - - Vince>

According to the Center for Science in the Public Interest, the same Dr Leon has also been a consultant for Cyberonics, the maker of the Vagus Nerve Stimulation System, a hoped-for successor of Electroconvulsive (Shock) Therapy, to treat depression. Forest Labs has also funded Dr Leon's research.

Another waiver was granted to Jean Bronstein, Mr Jones said, because she owned stock in two drug companies that make antidepressants.

Mr Jones also pointed out that another member, **Bruce Pollock**, was designated a non-voting member because he receives as much as \$10,000 per year serving on advisory boards or speakers' bureaus for SSRI makers Forest Labs, GlaxoSmithKline, and Pfizer.

<Bruce G. Pollock, M.D., Ph.D., The Rotman Research Institute, Baycrest Center for Geriatric Care, Toronto, Canada. Receives less than \$10,001 per year sitting on the advisory board and speakers bureau for an affected firm and receives less than \$5,001 per year teaching for an institution both affected by policy decisions for antidepressant drugs.

(<http://www.fda.gov/ohrms/dockets/ac/06/waivers/2006-4272w1-04-Leon-ack.pdf>; accessed 11/30/06) Has consulted for Forest, Janssen, Organon, Galen Holdings PLC, and GlaxoSmithKline; has received grant/research support from Pfizer, Janssen, Forest and GlaxoSmithKline; and is on the speakers or advisory boards for Lundbeck, Organon, Forest, Pfizer, Janssen, and GlaxoSmithKline.

(<http://archinte.ama-assn.org/cgi/content/abstract/164/3/327> and <http://www.psychiatrist.com/infopack/index.htm>; accessed 12/5/06) While serving on Glaxo's scientific advisory board, Pollock wrote a letter to the October 1998 Journal of Clinical Psychiatry about the antidepressant Paxil's "discontinuation symptoms" that closely followed a memo drafted by Glaxo's public relations firm; the p.r. firm suggested in the memo that Pollock, among others, send the letter. (ABC News, "Drug Maker Withheld Paxil Study Data," 12/9/2004, <http://abcnews.go.com/Health/print?id=311956>; accessed 12/11/2006]) - - Vince>

The FDA report released for the hearing stated in part: "When results are analyzed by age it becomes clear that there is an elevated risk for suicidality

and suicidal behavior among adults younger than 25 years of age that approaches that seen in the pediatric population."

However, the FDA is now trying to claim that the increased risk only occurs until people reach the age of 25, a claim that critics are saying is just plain silly. The theory is contrary to a study reported on May 1, 2006, by the London Free Press from Toronto's Institute for Clinical Evaluative Sciences, which showed seniors 66 and up who were prescribed SSRIs were nearly 5 times more likely to commit suicide during the first month on the drugs than those patients given the older class of drugs used to treat depression.

Records researcher, [Vince Boehm](#), who tracks all studies on SSRIs, says, "It makes no difference how old a person is, the danger is still there."

"I'll concede that maturity and life's experiences offer an arguably slim buffer of safety," he notes, "but this is an extremely fragile safety net." Mr Boehm says nothing magical happens at 2--5. "We've made a numbers game out of this," he warns, "a macabre form of Russian Roulette."

A leading expert on SSRIs, psychiatrist, [Dr David Healy](#), author of, [The Creation of Psychopharmacology](#), agrees and says, "The idea that you would have a risk in one age group but not in another is just wrong."

Dr Healy testified at the hearing about the manipulation of data from clinical trials. The industry controls the studies, and with the help of the FDA, he told the audience, drug makers have miscoded the data so that the articles in the medical journals that represent clinical trial data on the drugs are misleading.

Another SSRI expert, psychiatrist, Dr Peter Breggin, author of, "The Antidepressant Fact Book," also testified and said, "America's drug watchdog needs to come clean because it's been approving depressants as antidepressants."

"The primary data on suicidality," he said, "has been generated in short-term controlled clinical trials planned by drug companies, carried out by drug company hacks, and evaluated by drug company employees at corporate headquarters."

"If that kind of carefully cultivated evaluation bears such bad fruit," Dr Breggin noted, "imagine what the real data must show."

Many grieving family members testified and described the same kind of horror

stories that the FDA has been hearing since the first hearing on the dangers of SSRIs back in 1991.

Gwen Olsen, a former drug company sales representative, gave the panel a first-hand account of how easy it was to influence prescribing doctors by offering them free meals, gifts, and gimmicks to gain access and present them with manipulated data.

Ms Olsen now lives with the fact that her 20-year-old niece committed suicide while going through withdrawal from Paxil, first by trying to hang herself from a ceiling fan and when the fan broke, she doused herself with gasoline and set herself on fire.

Beverly Hatcher described her mother as having no history of depression but yet killed herself after 16 days on Paxil. Tony Noll, whose father also committed suicide, told the panel, "I came to speak to you on behalf of the statistically insignificant."

Rosemary Dorsett testified that her son was screened for depression during a physical, and was given Prozac by a GP, after which he became an insomniac, lost weight, heard voices, and shot himself in the chest. She emphasized that her son loved life and the suicide was totally out of character.

Mary Ellen Whitter also told the panel that her teenage daughter loved life and was happy until shortly after graduation when she was prescribed Paxil for sleep problems and anxiety, and hung herself 7 days later.

In total disregard of the drugs' new warnings, doctors continue to prescribe SSRIs to children all over the US. A study in the August 2006, Archives of General Psychiatry, found that children, aged 6 to 18, who took antidepressants for depression in an inpatient setting were 52% more likely to attempt suicide in the 60 days following discharge from the facility, than children who were not taking the drugs.

For this study, the researchers analyzed data from the national Medicaid Analytic Extract Files, including information from all 50 states, and determined that children who filled prescriptions for antidepressants after an inpatient stay were 15.62 times more likely to die by suicide than patients who were not taking antidepressants.

"These findings," said lead author, **Dr Mark Olfson, MD**, a professor of psychiatry at Columbia University, "serve to reinforce some of the concerns

that have been raised and really emphasize the importance of paying close attention to changes in mood and actions of severely depressed young people as they start antidepressant medication."

<Mark Olfson, M.D., M.P.H., Associate Professor, Department of Clinical Psychiatry, Columbia University; Clinical Psychiatrist, New York State Psychiatric Institute, New York. According to the New York Post (Drug-Company Gravy Train, 2/28/99, pg. 005), received speaking fees from McNeil Pharmaceuticals. -- Vince >

Despite the warnings on SSRI labels to watch patients closely for signs of suicidality, a recent study found that less than 18% of patients on the drugs received even the minimum level of follow-up care in the most critical time after being prescribed SSRIs.

According to the report in the August 2006, American Journal of Managed Care, nearly half of the patients had no follow-up visits during the first month, and fewer than 18% saw a practitioner for mental health follow-up care during that time.

Dr Healy says, all patients need to be warned that, if they feel strange or anxious they should return to their doctor. But his concern, he says, "is that doctors indoctrinated by drug company input and faced with a patient saying they feel worse will double the dose rather than reducing it or switching to a different treatment."