

Best Kept Secret - SSRIs Do Not Work

March 3, 2007. By Evelyn Pringle

Washington, DC: The medicalization of distress has led to a dramatic rise in the use of antidepressants, however it is questionable whether patients are being told that in controlled clinical trials the drugs barely outperformed a placebo, says Jonathan Leo, Associate Professor of Neuroanatomy, Lincoln Memorial University, DeBusk College of Osteopathic Medicine

Dr Leo also states that patients are not told that in many cases the symptoms of depression will improve within six months even without medication, or that many people have significant physiological problems when they try and get off the drugs. In the interest of informed consent, he notes, patients should be given all the facts before taking an antidepressant.

That said, the fact that the class of antidepressants known as the **selective serotonin reuptake inhibitors** (SSRIs), are basically useless in treating depression in children and adults is not news to the FDA. Back on September 23, 2004, during testimony at a hearing before the House Oversight and Investigations Committee on Energy and Commerce, Dr Robert Temple, the FDA's Director of the Office of Medical Policy, discussed the agency's review on the efficacy of SSRIs with the children.

He noted that it was important in a risk-benefit equation to understand the benefit side. "Of the seven products studied in pediatric MDD (Prozac, Zoloft, Paxil, Celexa, Effexor, Serzone and Remeron)," he testified, "FDA's reviews of the effectiveness data resulted in only one approval (Prozac) for pediatric MDD."

"Overall," Dr Temple said, "the efficacy results from 15 studies in pediatric MDD do not support the effectiveness of these drugs in pediatric populations."

Also in 2004, a study of previously hidden unpublished data as well as published studies on five SSRIs, was conducted by Tim Kendall, deputy director of the Royal College of Psychiatrists' Research Unit in London, to help analyze research to draw up the clinical guidelines for British regulators, and published in the *Lancet*.

Following his evaluation, Mr Kendall stated: "This data confirms what we found in adults with mild to moderate depression: SSRIs are no better than placebo, and there is no point in using something that increases the risk of suicide."

In 2005, the *British Medical Journal* published another study that concluded that SSRIs are no more effective than a placebo and do not reduce depression.

In December 2006, at the most recent FDA advisory committee meeting held to review studies on SSRI use with adults, SSRI expert, Dr David Healy, author of, "The Antidepressant Era," told the panel that the efficacy of SSRIs has been greatly exaggerated, while the actual studies reveal that only one in ten patients responds specifically to an SSRI rather than a nonspecific factor or placebo.

Critics complain that industry funded studies are presented in ways to exaggerate benefits and obscure side effects. "These include failure to publish negative results, the use of multiple outcome measures, and selective presentation of ones that are positive, multiple publication of positive study results, and the exclusion of subjects from the analysis," according to the paper, "Is Psychiatry For Sale," by Joanna Moncrieff, in *People's Voice*.

Mr Moncrieff says, psychiatry and the industry make a "formidable combination" because psychiatry derives its legitimacy from the view that mental disorders are equivalent to medical diseases. "Drug treatments that are aimed at specific diagnoses," she explains, "help to endorse this view, and the industry has the financial capacity to ensure that this view becomes

accepted and respectable."

"In turn," Ms Moncrieff writes, "the authority of psychiatry enables it to define what is considered as mental disorder and what is appropriate treatment, thus creating markets and opportunities for the pharmaceutical industry."

Critics are most concerned about the continued profit driven prescribing to children with full knowledge that SSRIs are dangerous and do not work with kids. "Drug companies have targeted children as a big market likely to boost profits and children are suffering as a result," says SSRI expert, psychiatrist, Dr Peter Breggin, founder of the International Center for the Study of Psychiatry and Psychology, and author of, "Toxic Psychiatry."

Kelly Patricia O'Meara, author of, *Psyched Out: How Psychiatry Sells Mental Illness and Pushes Pills That Kill*, prescribing SSRIs to kids must stop. "It is unconscionable," she states, "that it even occurs today given the serious warnings recently made mandatory by the FDA."

In the article, "A Prescription for Disaster," pediatrician, Lawrence Diller, author of, "The Last Normal Child," notes that child psychiatrists have long been viewed as the authorities in the evaluation and treatment of children's emotional and behavioral problems. "Today, however," he says, "these doctors appear to be pushing pills exclusive of anything else."

As an example, Dr Diller points to a survey of child psychiatry practices by the Yale Child Study Center, in the *Journal of the American Academy of Child and Adolescent Psychiatry*, that found that only one in 10 children who visit a child psychiatrist leaves without a prescription.

Child neurologist, Dr Fred Baughman, author of "The ADHD Fraud: How Psychiatry Makes Patients of Normal Children," also says, "pills are invariably prescribed in 91% of the first visits to a child psychiatrist."

According to Dr Baughman, we have 10 million of the 50 million school children in the nation on one or more psychiatric drugs. "This is death by psychiatry," he states.

The FDA approves drugs for uses and with patient populations that have been adequately tested. The term off-label means prescribing a medication for a different patient group, or at a different dose, duration, or combination with another drug, that has not been approved as safe and effective. While doctors may legally prescribe a drug for an unapproved use, drug makers are barred from promoting a drug for off-label uses but it's common knowledge that they do it on a regular basis.

The cost of off-label prescribing has become a major health problem in the US. According to the 2006, report, *Preventing Medication Errors*, by the Institute of Medicine, each year errors in the way drugs are prescribed, delivered and used, injure 1.5 million people in the hospital setting alone and cost more than \$3.5 billion a year to treat.

Medical experts warn that prescribing drugs to children that have been approved only for adults, is extremely dangerous because the correct dosage has not been established for their weight and developing body organs. According to patient rights activist, Doyle Mills, psychiatry is turning into Russian Roulette. "There is no known safe dose," he says, "for any of these psychiatric drugs in young children."

"They are never tested in the under-five population," Mr Mills says, "yet children can be given these drugs legally."

California Attorney, Ted Chabasinski, who handles cases involving patient rights and exposing the off-label marketing of psychiatric drugs, says, "the drug companies, and their subsidiary, the American psychiatric profession, push drugs for children that have never been shown to be beneficial, but clearly are dangerous and have many life-threatening effects."

According to Vera Sharav, Director of the Alliance for Human Research Protections, "The only

way to stop the prescribed assault on America's children is to put health care professionals (mostly psychiatrists) who prescribe toxic psychotropic drugs (and drug cocktails) for children--for whom these drugs have not been approved as either safe or effective--on trial in open court."

"Let the public bear witness," she states, "to the proceedings that will demonstrate the absence of scientific-medical evidence to support the widespread misprescribing of harmful drugs for children."

Evidence from many sources confirm that SSRIs commonly cause or exacerbate a wide range of abnormal mental and behavioral conditions, according to Dr Breggin. "These adverse drug reactions," he states, "include the following overlapping clinical phenomena: a stimulant profile that ranges from mild agitation to manic psychoses, agitated depression, obsessive preoccupations that are alien or uncharacteristic of the individual, and akathisia."

Each of these reactions, he explains, can worsen the individual's mental condition and can result in suicidality, violence, and other forms of extreme abnormal behavior.

SSRIs have been on the market less than 20 years so their long-term effects are still unknown. Barry Tuner, a professor of law and medical ethics in the UK, says mental illness has skyrocketed in the US because drug companies have marketed it and the US is facing a "societal catastrophe" if this is not reined in.

"In twenty years," he warns, "a huge percentage of the population will be damaged by these medications and the recipients will have real mental disorders caused by the drugs."

Studies are being conducted in attempt to assess the long-term damage on kids. Last year, Dr Amir Raz, assistant professor in the Division of Child and Adolescent Psychiatry at Columbia University, and researcher at the New York State Psychiatric Institute, writing in the journal PLoS Medicine, said mouse studies indicate exposure to SSRIs early in life produces abnormal emotional behaviors in adults.

"Some exploratory findings," Dr Raz wrote, "suggest that artificial perturbation of serotonin function in early life may alter the normal development of brain systems related to stress, motor development, and motor control."

Other medical experts warn that the harm caused to the body by psychiatric drugs is not limited to mental disorders. Dr Grace Jackson, author of, "Rethinking Psychiatric Drugs: A Guide for Informed Consent," points out that, "some physicians seem to only think these pills effect everything from the neck up, and they forget that when they give the medications there is an entire human body that may be feeling unanticipated effects of these medications."

Most patients, including parents acting on behalf of their children, know little if anything about off-label prescribing and assume that their doctors are giving them an approved drug for an approved use. But all too often, experts say, through no fault of their own, patients wind up with more serious health problems then they had to begin with due to off-label prescribing.