

Christopher Kratochvil, M.D.'s Testimony from FDA hearing on December 13, 2006.

Good morning. My name is Christopher Kratochvil, M.D, and I am a Child & Adolescent Psychiatrist at the University of Nebraska Medical Center in Omaha, NE. I have conducted research in mood disorders funded by the NIMH, as well as pharmaceutical companies. I paid for my own travel today on behalf of the American Academy of Child and Adolescent Psychiatry.

This morning I would like to make 3 points based upon the pediatric antidepressant experiences which may be useful to consider in today's deliberations: antidepressants are effective in the treatment of pediatric depression, antidepressant use has been correlated with a decrease in youth suicides, and the pediatric black box label was correlated with a significant decline in the use of antidepressants in children and adolescents.

First, as one of the principal investigators in the NIMH-funded Treatment for Adolescents with Depression Study, we demonstrated that fluoxetine, both alone and in combination with cognitive behavioral therapy, was safe and effective for the treatment of adolescent depression. Medication was important in improving the impairing symptoms of these youths, while cognitive behavioral therapy alone was no more effective than placebo.

Second, we demonstrated by Gibbons et al, in the Nov. 2006 American Journal of Psychiatry SSRI prescriptions have been associated with lower suicide rates in children. While no direct causation can be determined, this data is certainly congruent with previous data demonstrating declining suicide rates correlated with increases in antidepressant prescriptions.

Third, several psychopharmacoepidemiological studies have identified declining pediatric prescriptions for antidepressants since the 2004 black box label. For example, recent data presented by Thomason et al, demonstrated a 19.6% decline in new pediatric antidepressant prescriptions from one year before to one year after the black box. This decline was due in part to physicians who stopped treating depressed patients, as well as referrals to specialists with excessive waiting periods due to a significant workforce shortage, leaving many children and adolescents with depression with limited access to care.

It is obviously crucial to thoroughly assess the risks of any intervention, but the potential benefits, and risks of not treating, must be considered as well.

My concern is that heightened anxieties will result in a diminished appropriate use of these effective treatments, leading to unnecessary suffering, impairment, and possible loss of life.

I ask the committee to take these concerns into account when deliberating potential recommendations for the treatment of our patients suffering from depression.