FDA requires black box warning on all antidepressants

15 Oct 2004 "Food and Drug Administration (FDA) directed manufacturers of all antidepressant drugs to revise the labeling for their products to include a boxed warning and expanded warning statements that alert health care providers to an increased risk of suicidality (suicidal thinking and behavior) in children and adolescents being treated with these agents, and to include additional information about the results of pediatric studies."

The agency went on to cite "... recommendations made to the Agency at a joint meeting of the Psychopharmacologic Drugs Advisory Committee and the Pediatric Drugs Advisory Committee on September 13-14, 2004."

For full text see FDA Public Health Advisory October 15, 2004 (http://www.fda.gov/cder/drug/antidepressants/SSRIPHA200410.htm)

Also relevant are comments by Dr David Fassler, M.D. (http://www.fda.gov/cder/drug/antidepressants/SSRIPHA200410.htm) who is a Trustee of the American Psychiatric Association (http://www.psych.org) , Fellow of the American Academy of Child and Adolescent Psychiatry (http://www.aacap.org) , member of the Board of the Federation of Families for Children's Mental Health (http://www.aacap.org) , and Clinical Associate Professor of Psychiatry at the University of Vermont College of Medicine (http://www.aacap.org) .