

*****FINAL*****

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2006N-0414 Suicidality Data from Adult Antidepressant Trials
Division of Dockets Management (HFA-305)
Food and Drug Administration
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Rockville, MD 20852

The American Academy of Child and Adolescent Psychiatry (AACAP) appreciates the opportunity to submit this statement to the FDA Psychopharmacologic Drugs Advisory Committee regarding the meta-analysis of suicidality data from adult antidepressant trials. Such review is vital to determining the risks of any medication treatment.

The AACAP is a medical membership association established by child and adolescent psychiatrists in 1953. With over 8,000 members, the AACAP is the leading national medical association dedicated to treating and improving the quality of life for the estimated 7 - 12 million American youth under 18 years of age who are affected by emotional, behavioral, developmental and mental disorders. Our members are specialists who diagnose and treat children, adolescents and adults with mental illnesses. The AACAP supports research, continuing medical education and access to quality care. We are acutely concerned about the safety of the medications that may be used in treatments and appreciate the Committee's concern and attention to the suicidality data from adult antidepressant trials.

The AACAP would like to thank the FDA Psychopharmacologic Drugs Advisory Committee for holding the hearing on December 13, 2006. Depression is a serious medical illness potentially fatal because of the risk of suicide. However, when recognized and correctly diagnosed, it can be treated successfully. Effective therapeutic approaches include medication, psychotherapy, or both, individualized to the needs of the patient.

In late 2004, the FDA warned of the potential risk of the use of antidepressants in children and adolescents due to a review of conflicting data that indicated an increase in suicidal thoughts and/or behaviors of depressed children and adolescents while taking antidepressants. In June 2005, the AACAP and the American Psychiatric Association (APA) asked the American Medical Association (AMA) to conduct an independent review of the research data pertaining to the safety and efficacy of the use of antidepressants in the treatment of child and adolescent psychiatric disorders. The 2005 AMA Report of the Council of Scientific Affairs CSA Report 10-A-05 indicated that "a causal role for antidepressants in increasing suicides in children and adolescents has not been established." It went on to state that the "concerns that antidepressants potentiate suicidal or self-injurious behavior need to be balanced by the clear risk of suicide in children and adolescents with untreated depression."

Several scientific studies agreed with the AMA report. The study conducted by Robert Gibbons, Ph.D., et al., published in the *American Journal of Psychiatry* in November 2006, examined the association between child and adolescent antidepressant prescription and suicide rates on a national level. This study showed that “SSRI prescriptions are associated with lower suicide rates in children and may reflect antidepressant efficacy, treatment compliance, better quality of mental health care, and low toxicity in the event of a suicide attempt by overdose.” The report by Gibbons et al is consistent with the study published by Mark Olfson, M.D., et al., in the *Archives of General Psychiatry* in 2003, with both studies reporting a strong correlation between the decline in suicide attempts in children and adolescents prescribed antidepressants.

Open studies of adult populations have also found that no increased risk of suicide occurred among antidepressant users. Studies published by Wayne D. Hall, Ph.D., et al. in the *British Medical Journal* 2003, Gregory Simon, M.D., M.P.H., et al. in the *American Journal of Psychiatry* 2006, and Robert Valuck, Ph.D., et al. presented at the 2005 American College of Neuropsychopharmacology conference have all concluded that a strong correlation exists between a decline in suicide attempts and suicide in adults prescribed antidepressants in open trials.

The FDA black box warning placed on antidepressants in October 2004 describing an increased risk of suicidality among children and adolescents prescribed these medications has caused concerns for medical professionals. Given the severe shortage of mental health professionals, many primary care physicians provide the only medical role available for treatment of pediatric patients with depressive disorders. Following the FDA warning, these physicians began to hear families’ concerns based on media reports containing conflicting information regarding the use of antidepressants, resulting in refusals to initiate antidepressants. In response to the FDA’s warning and family concerns, physicians, including specialists, have reduced prescribing of antidepressants. Some physicians have changed treatment practices to prescribing alternative psychotropic medications, while others stopped treating these patients, instead referring them to child and adolescent psychiatrists. Unfortunately, this country is facing a severe shortage of child and adolescent psychiatrists leading to excessive waiting periods for patients in need. This dramatic shift raises questions of whether those children and adolescents with depression who are no longer taking antidepressant medications are receiving any care at all.

The AACAP is supportive of the FDA’s practice of approving safe and effective treatments for our patients. We strongly urge the FDA Psychopharmacologic Drugs Advisory Committee to consider all data available on the relationship of antidepressant prescription rates and suicide when determining decisions about product labeling. While protecting and informing the public, we urge the agency to balance the impact of black box warnings on current practice and the demonstrated effectiveness of these medications to treat adults with depression.