

AMERICAN ACADEMY OF
CHILD & ADOLESCENT
PSYCHIATRY



April 8, 2004

Jan Johannessen, M.D.
Office of the Commissioner (HF-33)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Johannessen,

The American Psychiatric Association (APA) and the American Academy of Child and Adolescent Psychiatry (AACAP) are pleased to provide written comments to the Science Board to the Food and Drug Administration (FDA).

APA is the nation's oldest medical specialty society, founded in 1844, with over 35,000 members nationwide specializing in the diagnosis, treatment and prevention of mental illnesses including substance abuse disorders. The AACAP is a medical membership association established by child and adolescent psychiatrists in 1953. With over 7,000 members, the AACAP is 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. The APA and AACAP support research, continuing medical education and access to quality care.

In testimony to the United States Senate's Health, Labor and Pensions Committee on March 1st, 2005, we also suggested Congress consider the creation of an independent body to oversee and advise the FDA on post-marketing issues.

Many of the clinical trials currently conducted in conjunction with the approval of a new medication are relatively short-term. However, like adults, children and adolescents often take medication for an extended period of time. The APA and the AACAP support both larger scale and longer studies on the safety and efficacy of medications used in the treatment of pediatric patients. Although it is often impractical to complete long-term studies prior to drug approval, such studies should always be conducted as part of the long-term plan for the medication. Data from these trials should also be included in a centralized registry, accessible to the general public. Physicians and parents need and deserve access to such information in order to make appropriate decisions regarding treatment options.

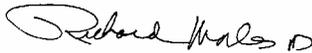
The AACAP and the APA call for new research on SSRIs to ensure that these medications are used in the safest and most effective manner possible. The FDA should expand and strengthen post-marketing surveillance and increase funding for long term follow up. With respect to the SSRI antidepressants, several large scale NIMH funded ongoing studies are

currently underway which will significantly enhance our knowledge regarding the use of these medications in children and adolescents. These include TADS (Treatment for Adolescents with Depression Study), TASA (Treatment of Adolescent Suicide Attempters), and TORDIA (Treatment Of Resistant Depression In Adolescents). The results of these studies will help us refine our ability to determine which children and adolescents are most likely to respond to a specific intervention.

The APA and AACAP propose" the development of a Pediatric Central Nervous System Advisory Committee which could provide input, as necessary, to enhance the FDA's ability to respond to such issues as the small number of patients available for study. That is particularly important where a side effect may be identical in appearance to the natural history of the disease, such as in depression. It is particularly challenging to evaluate potential side effects which are similar or even identical to symptoms associated with an underlying illness. FDA made an attempt at this challenge with respect to the SSRI antidepressants. In its process, FDA may not have fully considered the broad range of clinical and treatment related variables associated with the use of these medications. This observation underscores the importance of ensuring that the FDA has access to and input from queries researchers and clinicians with appropriate background and expertise to assist regulators in distinguishing between side effects and underlying symptoms.

Thank you for the opportunity to comment regarding the need for expanded FDA post-marketing surveillance.

Sincerely,



Richard Sarles, M.D.
President
American Academy of Child
and Adolescent Psychiatry



James H. Scully Jr., M.D.
Medical Director
American Psychiatric Association

**American Academy of Child & Adolescent
Psychiatry**
Department of Government Affairs and Clinical
Practice
3615 Wisconsin Avenue, NW
Washington, DC 20016
Telephone: 202.966.7300
Fax: 202.966.1944

American Psychiatric Association
Division of Government Relations
1000 Wilson Blvd, Suite 1825
Arlington, VA 22209
Telephone: 703.907.7800
Fax: 703.907.1083