**APA Briefing Sheet**

November 2004

**Recent Federal Activity Concerning**
**Antidepressant Use and Suicide Risk For Children**

The potential for increased suicide risk for children with the use of a certain class of antidepressants (i.e. selective serotonin reuptake inhibitors (SSRIs)) first gained attention in the U.S. after the British released information indicating risks associated with the use of the SSRI Seroxat (Paxil) with children. In the spring of 2003, the British Medicines and Healthcare Products Regulatory Agency conducted a comprehensive review of clinical trials examining the use of Seroxat with children. The findings indicated that Seroxat was ineffective and that a larger proportion of those children taking it thought about committing suicide than in the placebo control group. Subsequently, the drug is no longer allowed to be prescribed for children in Britain.

## FOOD AND DRUG ADMINISTRATION (FDA)

### Advisory Committee Hearings

Hearings on February 2, 2004, focused on the analysis of 25 clinical trials that showed evidence of a link between the use of certain antidepressants and suicidal tendencies among youth. While testimony indicated that no suicides occurred among the approximately 4,000 children who participated in the clinical studies, preliminary data suggested that suicidal behavior, while infrequent, might be at least twice as frequent among some antidepressant users. Furthermore, it should be noted that Prozac is the only SSRI approved by the FDA for use with children.

The FDA Psychopharmacological Drugs Advisory Committee and the FDA Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee Regarding Suicide and the Use of Antidepressants by Children held meetings on February 13 and 14, 2004. The Committee and Subcommittee reviewed published and unpublished research, and concluded that two to three out of every 100 young people treated with antidepressants might be at increased risk of suicidal behavior.

Ultimately, the FDA's Advisory Committee recommended that the FDA require manufacturers of antidepressants to add a "black box" warning label indicating a potential association with suicidal thoughts and behavior in children and adolescents.

### Labeling

In March of 2004, the FDA adopted the recommendation of its advisory committee to require manufacturers to include a warning on antidepressant labels that the drug could lead some patients, adults and children, to become suicidal.

On October 15, 2004, the agency ordered that over 30 antidepressants, including SSRIs, carry a "black box" warning label indicating: "Antidepressants increase the risk of suicidal thinking and behavior (suicidality) in children and adolescents with major depressive disorder (MDD) and other psychiatric disorders."

## CONGRESSIONAL ACTION

### Hearings

The House Energy and Commerce Subcommittee on Oversight and Investigations held a hearing on September 9, 2004, to examine the publication and disclosure issues concerning antidepressant pediatric clinical trials. Representatives from major pharmaceutical companies (including Forest Laboratories and Glaxosmithkline), the FDA, American Medical Association, Pharmaceutical Research and Manufacturers of America, and the American Academy of Pediatrics testified. The lack of public knowledge about this issue and the risks posed to children taking certain antidepressants were highlighted.

This House subcommittee held another hearing on September 23 to examine the FDA's research on the safety and efficacy of antidepressant drug use in children. Subcommittee members asked questions to shed light on the claim that the FDA repeatedly pressured Dr. Andrew Mosholder, an FDA medical researcher, to withhold from publishing conclusions drawn from his and other pediatric clinical trials, which indicate an increased risk of suicidal thoughts and behavior among children on particular antidepressants. Discussion also addressed why the FDA did not take action sooner regarding these concerns. The witness list included Dr. Mosholder and Dr. Robert Temple, Director of the Office of Medical Policy, as well as other FDA representatives.

### Legislation

The Fair Access to Clinical Trials (FACT) Act was introduced on October 7th by Senators Christopher Dodd (D-CT), Edward Kennedy (D-MA), Tim Johnson (D-SD), and Ron Wyden (D-OR). The legislation would require pharmaceutical companies to post clinical trial information publicly (e.g., on the Internet) and mandate that all trials be registered in the database of The National Institutes of Health's Website

(clinicaltrials.gov) in order to attain approval from U.S. institutional review boards. It would also expand the FDA's authority, enabling them to correct false or misleading information about clinical trial results. Representatives Henry Waxman (D-CA) and Edward Markey (D-MA) introduced a House companion bill that would establish a mandatory registry for clinical trials of drugs and biologics.

The issue of SSRIs and suicide among youth was also addressed by Rep. Ron Paul (R-TX) in a bill opposing universal mandatory mental health screening. The controversy surrounding the FDA's failure to disclose clinical trial findings that suggest an increased risk of suicidal thoughts and behaviors in children on antidepressants is mentioned in this bill.

**INVOLVEMENT BY NATIONAL ORGANIZATIONS**

**American Psychological Association Working Group on Psychoactive Medications for Children and Adolescents**
APA established a working group to review current literature on the effective use, sequencing, and integration of psychoactive medications and psychosocial interventions for children and adolescents. Their mission encompasses the development of a comprehensive report that includes a comparative examination of the risk-benefit ratio of psychosocial and pharmacological treatments, and the range of child and adolescent psychopharmacology.

**American College of Neuropsychopharmacology Task Force**
The task force reviewed clinical trials of more than 2,000 youth and did not find a significant increase in suicidal thoughts or behaviors. In addition, they concluded that the benefits of SSRIs outweigh the risks and that suicide is likely caused by underlying depression, not the medication. Findings, however, were only preliminary because the clinical trials studied did not include a substantial amount of data from the FDA or pharmaceutical companies.

**National Alliance for the Mentally Ill (NAMI) Policy Research Institute Task Force**
In June 2004, a NAMI task force issued an advisory statement regarding prescribing psychotropic medications to children. The report emphasized the necessity for parents to be fully informed about the potential risks and benefits before the medication is prescribed for their children. In addition, the report indicated that while psychotropic medications can be lifesaving, children and adolescents should be closely monitored and evaluated for negative side effects.

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Mental health help for children

# Should our children be taking psychotropics?

**An APA group is reviewing children's use of psychoactive medications and will examine psychologists' current and future roles in the area.**

**BY TORI DeANGELIS**
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An APA working group is taking a serious look at one of the most controversial areas in children's mental health: prescribing psychoactive medications to children and adolescents. The group first met shortly after the Food and Drug Administration (FDA) issued a "black box" warning--its strongest safety alert--linking antidepressants to increased suicidal thoughts and behavior in children and teens.

The Working Group on Psychoactive Medications for Children and Adolescents, chaired by Ronald T. Brown, PhD, an expert in pediatric psychology and dean of Temple University's College of Health Professions, will review the scientific literature in the area. The group, established by APA's Board of Directors in March, housed in APA's Public Interest Directorate and appointed by APA President Diane Halpern, PhD, met for the first time Nov. 19-21 and will continue their work in 2005.

"The bottom line is there's more use of psychotropic medication with children than there is research data on it," says Brown, author of several books on the topic, including one in progress, "Medications for Children: A Guide for the Practitioner" (Guilford Press). "Our purpose is to come up with the state of the art about what is known and to advocate for the best interests of the child."

The eight-member group--which includes experts on childhood depression, anxiety, attention-deficit hyperactivity disorder (ADHD) and regulatory issues, as well as a child psychiatrist--will focus and write a report on the bigger picture of what is and isn't known about the effects of such medications on children--and how to best apply that knowledge in practice, says Brown.

"The question is, how do we best treat these kids, and do these psychotropic medications that have routinely been used to treat kids meet the scrutiny of science?" he says.

At least one class of psychotropic medications used with children, antidepressants, is under strong scrutiny after British studies showed they cause suicidal tendencies in 2 percent to 3 percent of child users, the impetus for the Oct. 15 FDA action on the matter. At present, more than 6 percent of American children and adolescents are estimated to take some kind of psychiatric medication. With the exception of ADHD drugs, many of those medications are not yet approved by the FDA

for use with children, but prescribed by medical practitioners based on their judgment and experience.

Two child experts--the University of Puget Sound's Barry Anton, PhD, an APA Board of Directors and Council of Representatives member, and the University of Kansas's Michael C. Roberts, PhD, an APA council member--conceived of the group in response to public concern over a 2003 Archives of Pediatrics and Adolescent Medicine study (Vol. 157, No. 1) reporting a two- to three-fold increase in psychiatric drug use among children and teens between 1987 and 1996. (In 2000, the study's principal investigator, Julie Magno Zito, PhD, of the University of Maryland, re-evaluated one of the health plans investigated in the study and found that usage rates had continued to rise.)

Anton and Roberts also wanted the working group to discuss psychologists' current and future roles in the area, both as health-care consultants and as potential future prescribers, Anton says. Many psychologists already inform family practitioners and pediatricians on the state of the science on psychotropics for children, so there is good reason, he explains, to create consensus on what psychologists know and what they are communicating to other practitioners. In addition, as psychologists continue to gain prescription privileges, including for children, it is important their knowledge base is solid, Anton notes.

The group's aim is not to demonize psychotropics, adds Brown, but rather to take a scientifically open stance toward the use of these medications and acknowledge the good that drugs can do when used appropriately. For instance, despite their potential for misuse or overuse, ADHD medications such as Ritalin have been well-researched and proven very helpful in treating the condition, he notes. (Two major ongoing National Institute of Mental Health-funded studies of ADHD--the Multimodal Treatment Study of ADHD and the Preschool ADHD Treatment Study--promise more information in the near future on positive and side effects of these medications, as well as on the efficacy of nonpharmacological behavior treatments.)

Task force members are David Antonuccio, PhD, of the University of Nevada; George DuPaul, PhD, of Lehigh University; Mary Fristad, PhD, of Ohio State University; Cheryl King, PhD, of the University of Michigan; William Pelham, PhD, of the State University of New York at Buffalo; John Carl Piacentini, PhD, of the University of California, Los Angeles; and Benedetto Vitiello, MD, of the National Institute of Mental Health.

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