

News RELEASE

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APA Urges Caution, Research & Disclosure on Antidepressants

Arlington, Va. - In oral and written testimony, the American Psychiatric Association (APA) said today at a Food and Drug Administration (FDA) hearing that caution, additional research and full disclosure are needed with respect to a group of antidepressants known as selective serotonin reuptake inhibitors, or SSRIs. The APA also said that, because a significant minority of children and adolescents with depression do not respond to an initial medication, it is important for physicians and patients to have access to a full range of medications to treat pediatric depression – an illness with significant long-term consequences, including an increased risk for suicide.

The FDA hearing was a joint session of two committees of the regulatory agency: its Psychopharmacologic Drugs Advisory Committee and the Pediatric Subcommittee of its Anti-Infective Drugs Advisory Committee. David Fassler, M.D., an APA trustee who is a practicing child and adolescent psychiatrist in Vermont, delivered oral testimony on behalf of the APA. The APA's director of research, Darrel A. Regier, M.D., M.P.H., analyzed all current, publicly available research on SSRIs, especially with respect to their use in treating pediatric depression, which is the basis for the written statement APA submitted to the FDA.

“Every suicide is a tragedy, and any increased risk of suicidal thoughts or behaviors, no matter how small, must be taken very seriously,” said Dr. Fassler. He added that, based on the data currently available, “Most clinicians believe, and I would concur, that for children and adolescents who suffer from depression, the potential benefit of these medications far outweighs the risk.”

Dr. Regier concurred: “Rigorous research has demonstrated that, when accurately diagnosed, childhood and adolescent depression is highly amenable to effective and appropriate treatments.”

He pointed to the federally funded Treatment for Adolescents with Depression Study (TADS) results, which found in part that patients responded positively to a combination treatment – an SSRI (fluoxetine) plus Cognitive-Behavioral Therapy, a form of talk therapy – at a rate of 71 percent – double the 35 percent response rate for patients on placebo.

“Even in the case of the most effective combination treatment in TADS, 30 percent of patients did not improve, underscoring the need for a range of medications and psychotherapeutic interventions that are responsive to the unique characteristics of individual patients,” said Dr. Regier. “Further research is urgently needed to address treatment resistant depression.”

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The APA made several recommendations to policymakers in its statements:

- The development of a public clinical trials registry. The APA and the American Academy of Child and Adolescent Psychiatry secured the American Medical Association's support for the concept, which affects all of medicine and would help physicians and parents make fully informed decisions about treatment options.
- The continuation of current FDA warnings with respect to SSRIs – warnings that are appropriate and consistent with the scientific data.
- And, the intensification of research into the safety and efficacy of SSRIs through additional large-scale studies.

To see the full text of Dr. Fassler's oral statement, follow this link:

http://psych.org/advocacy_policy/reg_comments/fdapsychopharma.pdf

To see the full text of the written statement coordinated by Dr. Regier, follow this link:

http://psych.org/advocacy_policy/reg_comments/fdapsychopharmatestimony.pdf

The American Psychiatric Association is a national medical specialty society, founded in 1844, whose more than 35,000 physician members specialize in the diagnosis, treatment and prevention of mental illnesses including substance use disorders. For more information, visit the APA Web site at www.psych.org

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