

# News RELEASE

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## **APA Statement on the FDA's Hearing on Antidepressant Use in Pediatric Patients**

Arlington, Va. – The American Psychiatric Association (APA) released the following statement today in response to the recent Food and Drug Administration (FDA) hearing on antidepressant use in pediatric patients and further appropriate warnings:

The American Psychiatric Association commends the Food and Drug Administration, and in particular its Psychopharmacologic Drugs Advisory Committee and its Pediatric Advisory Committee, for its public hearing on safe antidepressant use in pediatric patients. The APA believes the hearing, held Sept. 13-14, was inclusive and thorough, and based on science and concern for patients and parents.

The APA also commends the advisory committees for recommending that the FDA maintain access to antidepressant medications. As part of a comprehensive treatment plan, antidepressants can be extremely helpful and even lifesaving for many young people struggling with depression, an illness with significant long-term consequences, including an increased risk for suicide. We believe the biggest threat to a depressed child's well-being is to receive no care at all.

The APA supports the advisory committees' recommendation that the FDA maintain access to a full range of antidepressants. As we stated during our testimony, the latest research indicates that between 30 percent and 40 percent of young people with depression will not respond to an initial medication. However, many of these patients will ultimately respond to a different medication. It is essential that physicians be able to utilize the full range of medications.

We believe that, by calling attention to the need for caution in prescribing antidepressants in this population and by calling for more research, the FDA has provided a valuable service in protecting the safety of the public while enhancing the knowledge base. The APA is hopeful that the hearing serves patients by adding to the dialogue between physicians, patients and families.

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It is key to note that the advisory committee's recommendation for "black box" warnings was adopted by a split vote, with 15 committee members in favor and eight opposed. The APA believes that several dissenters' concerns that such warnings will limit access to care are valid and should be taken into account by the FDA as it proceeds.

The APA believes the advisory committees have established a strong case for closer monitoring of patients with depression, especially vulnerable youngsters. The APA will look for continued opportunities to offer expert clinical advice to the FDA as it considers further appropriate warnings for antidepressants. In addition, we will work with physicians – including pediatricians and general practitioners – to help them better understand their patients' needs and properly monitor patients.

David Fassler, M.D., an APA trustee who is a practicing child and adolescent psychiatrist in Vermont, delivered oral testimony at the FDA hearing on behalf of the APA. To see the full text of Dr. Fassler's oral statement, follow this link:

[http://psych.org/advocacy\\_policy/reg\\_comments/fdapsychopharma.pdf](http://psych.org/advocacy_policy/reg_comments/fdapsychopharma.pdf)

The APA's director of research, Darrel A. Regier, M.D., M.P.H., analyzed all current, publicly available research on SSRI antidepressants, especially with respect to their use in treating pediatric depression, which is the basis for the written statement APA submitted to the FDA. 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](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](http://www.psych.org)**

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