

# NEWS RELEASE

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## APA Responds to FDA's New Warning on Antidepressants

**Arlington, Va.** – The American Psychiatric Association (APA) released the following statement in response to today's Food and Drug Administration (FDA) announcement of new warnings for antidepressants, especially when used in treating pediatric patients. The statement was issued on behalf of APA President Michelle B. Riba, M.D., M.S., and President-elect Steven S. Sharfstein, M.D.:

The American Psychiatric Association believes antidepressants save lives. As part of a comprehensive treatment plan, antidepressants can be extremely helpful 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.

We restate our continued deep concern that a "black box" warning on antidepressants may have a chilling effect on appropriate prescribing for patients. This would put seriously ill patients at grave risk. Recent prescription data suggest the current controversy over antidepressants has already lowered treatment rates; the new black box warning may further negatively impact treatment rates. The APA is working to help mitigate such an impact by collaborating with non-psychiatric physicians – including pediatricians and general practitioners – to help them better understand their patients' needs and properly diagnose, treat and monitor patients. Additionally, we hope the FDA will set in place a system to track the impact of the black box warning on prescribing patterns. This system should also track any increase in actions by patients to harm themselves as a result of reduced access to medically necessary treatment with antidepressants.

We are heartened that the FDA's newly issued black box warning on antidepressants includes our recommendations for: 1) close monitoring of patients by physicians, families and caregivers; 2) the need for caution in diagnosing and treating pediatric depression; and 3) disclosure of data from antidepressant clinical trials involving children and adolescents. We are also hopeful that the patient information sheet ("Medication Guide") developed by the FDA will serve these patients by adding to the dialogue between physicians, patients and families.

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It is important to understand that discriminatory insurance coverage of mental illnesses is a significant barrier to appropriate care and the close monitoring the FDA now advises. We call on Congress to pass the Wellstone Mental Health Equitable Treatment Act to ensure patients have access to adequate insurance coverage. We also urge federal and state governments to act promptly to remove barriers to care.

Lastly, we are concerned that publicity around the new warning may cause some successfully treated patients to stop taking antidepressants. An abrupt withdrawal could compound the problem by producing serious side effects. Physicians must understand their patients' concerns and work with them to determine the best course of treatment. Patients who choose to end medication should talk to their physician first.

**The American Psychiatric Association is a national medical specialty society, founded in 1844, whose nearly 36,000 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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