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Sept. 2, 2005

Release No. 05-53

**Analysis Confirms Impact of FDA Warning and Raises Concern for Kids, APA Says
*Joint Letter to FDA Urges Monitoring of Impact***

Arlington, Va. – On the heels of a new analysis revealing a “swift and steep” decline in antidepressant prescriptions dispensed to youth 18 and under, today the American Psychiatric Association (APA) and the American Academy of Child and Adolescent Psychiatry (AACAP) issued a joint letter to the U.S. Food and Drug Administration (FDA), once again urging the agency to monitor the impact of its regulatory action.

The news analysis appears in the current issue of *Psychiatric News* and is based on a two-year dataset provided NDC Health Inc. The analysis shows a statistically significant drop in prescribing of nearly 20 percent for this age group following FDA warnings.

“This dramatic shift raises the serious questions of whether those children and adolescents with depression who are no longer taking these medications are receiving any care at all – or are receiving the most effective care,” APA President Steven S. Sharfstein, M.D., and AACAP President Richard Sarles, M.D., wrote in their letter to FDA Commissioner Lester Crawford, D.V.M., Ph.D.

In October of last year the FDA issued a black box warning on antidepressants, which appears to have spurred the abrupt decline, “whose public health consequences are unknown,” according to the letter. The APA, the AACAP and the American Medical Association have urged the FDA establish a system to track the black box warning’s impact on prescribing patterns, as well as to track any increase in actions by patients to harm themselves as a result of reduced access to medically necessary treatment with antidepressants.

In full, Drs. Sharfstein and Sarles wrote:

The American Psychiatric Association and the American Academy of Child and Adolescent Psychiatry are dedicated to the care and effective treatment of patients with mental illnesses. In particular, we care deeply about children and adolescent struggling with depressive disorders.

We write to you today to furnish the U.S. Food and Drug Administration with a new analysis of antidepressant prescription patterns, which appears in the Sept. 2, 2005, issue of *Psychiatric News*, and to once again formally request that the FDA monitor the impact of the black box warning on antidepressants it issued on Oct. 15, 2004. The analysis reveals a swift and steep decline in antidepressant prescriptions dispensed to youth 18 and under – a decline whose public health consequences are unknown and must be monitored by policymakers, physicians, parents and patients.

(more)

Specifically, the analysis, based on a two-year dataset provided by NDC Health Inc., shows a statistically significant drop in prescribing of nearly 20 percent for this age group. This dramatic shift raises the serious questions of whether those children and adolescents with depression who are no longer taking these medications are receiving any care at all – or are receiving the most effective care. Several studies, including the Treatment of Adolescents with Depression Study (TADS), funded by the National Institute of Mental Health, have shown a combination treatment (medication and talk therapy) as being most effective for youngsters with depression – a course of treatment that would appear to be endangered by such a strong decline in the medication portion of therapy.

Moreover, under-treatment of teen depression is well documented, including in the U.S. government's Mental Health: A Report of the Surgeon General. This shift is additionally disturbing to us because it comes at a time when we should be doing more to help children and adolescents with depression, not less. The biggest threat to a depressed young person's well-being is to receive no care at all.

On Oct. 15, 2004 – the day the FDA issued the warning – the American Psychiatric Association asked “the FDA [to] 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.” The American Academy of Child and Adolescent Psychiatry also made a similar request at the time.

On June 21, 2005, the American Medical Association joined APA and AACAP in urging the FDA to evaluate the impact of its regulatory action on treatment patterns, patient compliance and patient access. Yet Psychiatric News reports that, upon forwarding its analysis and the NDC Health dataset to FDA officials, it was acknowledged on the record that the FDA “has not systematically tracked antidepressant prescribing in the pediatric population.” We would welcome the opportunity to work with the FDA to develop a sound methodology for measuring the effects of the warning.

We once again urge your agency to monitor the potential adverse consequences of this regulatory action, and we look forward to working with you to answer these vital public health questions.

The new analysis by Psychiatric News' senior staff writer Jim Rosack may be viewed at:
<http://pn.psychiatryonline.org/cgi/content/short/40/17/1-a>

The FDA's initial response to the analysis is available at:
<http://pn.psychiatryonline.org/cgi/content/full/psychnews;40/17/39>

Parents and physicians can access practical information on antidepressants, based on the latest science and medicine, at: www.ParentsMedGuide.org

About the American Psychiatric Association:

The American Psychiatric Association is a national medical specialty society whose more than 37,000 physician members specialize in the diagnosis, treatment and prevention of mental illnesses including substance use disorders. Healthy Minds. Healthy Lives. Care that works to get your mind healthy again so you can lead a healthy life. Visit APA at www.psych.org and www.healthyminds.org.

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