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Strattera Suicidal Thinking Data Is Of Little Clinical Significance, Lilly Consultants Say

Data used as the basis for a public health advisory linking Lilly's attention deficit/hyperactivity disorder therapy Strattera to suicidal thoughts in children and adolescents is of "little clinical significance," according to SUNY Upstate Medical University Research Professor of Psychiatry Russell Barkley.

"I, for one, do not see this information as impacting clinical practice in any significant way until we can understand the information better," he stated.

Barkley addressed the safety of atomoxetine at a press briefing hosted by Lilly Oct. 7.

FDA issued the public health advisory Sept. 29, advising that children and adolescents taking Strattera be closely monitored for changes in behavior after an analysis of clinical trial data showed a small but statistically significant increase (0.4% vs. 0%) in suicidal thinking in children taking atomoxetine compared with placebo (1"The Pink Sheet" DAILY, Sept. 29, 2005 <http://www.thepinksheetdaily.com/fdcreports/story/viewStory.do?targetAN=14050929002>).

Barkley said the validity of the data, which is from an analysis of 12 clinical studies, should be questioned because it is not based on a systematic clinical trial of suicidal ideation or suicide attempts.

"In a research project, we would be questioning all of the subjects using a standard protocol of questions, as to make sure that there are no significant variations," he said. " Then we could take that information and compare kids in treated groups versus placebo groups and have a little more confidence in what the numbers mean."

The existing analysis is especially unreliable because suicidal thinking is very common among adolescents, he added. Approximately 4%-8% of children 12 or younger have some suicidal ideation, and that figure jumps to 20%-30% among teenagers, Barkley said.

"One of the things that concerns me greatly here is the report of zero in the placebo groups," he noted. "It would indicate that the placebo group is a super normal group of individuals who have never thought about suicide, and of course that's not the case either."

In addition to his work at SUNY, Barkley works as a consultant to Lilly.

Columbia University Medical Center Professor of Psychiatry Laurence Greenhill,

another Lilly consultant, concurred. He advised physicians to make decisions regarding Strattera treatment based on a benefit/risk ratio.

"We have a very definite benefit and a very, very weak - but the analysis indicates present - risk," he stated.

Lilly Medical Director-Neuroscience A.J. Allen pointed out, however, that given the seriousness of the events and the patient population, the company and FDA feel the concern is high enough to warrant a label change.

The company plans to add a "black box" warning to the label after finalizing the content with FDA.

"This points out that we need to do more studies. There needs to be more research on this," Allen said. "That is really where we are. Until those things are in, it is fair to say, we did see something, and we need to do what's right in terms of patients and families."

- Jessica Merrill