



**TESTIMONY OF DR. THOMAS SULLIVAN  
ON BEHALF OF THE AMERICAN ACADEMY OF  
PEDIATRICS**

**THE FOOD AND DRUG ADMINISTRATION  
PEDIATRIC ADVISORY COMMITTEE**

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Thank you for the opportunity to provide comments to the Pediatric Advisory Committee of the Food and Drug Administration.

My name is Dr Thomas Sullivan and I am a pediatrician with 36 years of clinical experience treating children. I am here today in an official capacity representing the American Academy of Pediatrics (AAP).

Attention Deficit/Hyperactivity Disorder (ADHD) is a real disease that causes significant impairment in many children and adults. A careful and accurate diagnosis of ADHD should be made prior to starting stimulant treatment. The American Academy of Pediatrics developed a guideline for the diagnosis of ADHD in children ages 6 to 12 years, which can be referenced for this age group.

The AAP has also developed a guideline on the treatment of ADHD which notes that for people suffering impairment from ADHD, there are effective treatments, including prescription of stimulant medications.

Reports that have been received by the FDA point to a possible increased risk of cardiac events in people being treated with stimulants. The American Academy of Pediatrics urges the FDA to pursue further studies to determine whether or not stimulants actually cause these problems and whether or not these problems occur more frequently in people on stimulants than in other people.

One way to identify and follow the children and youth with ADHD in order to evaluate their treatments and the side effects of their prescribed drugs would be through a national registry.

Until studies have answered the questions about cardiac side effects, the AAP agrees it would be prudent to revise the labeling of stimulants in such a way as to alert clinicians to possible cardiac side-effects, particularly in people with known structural cardiac defects. Such labeling should be consistent across all stimulant preparations.

Rather than a black box warning to highlight these concerns, the AAP recommends that the FDA require manufacturers to send a letter to physicians letting them know the findings that led to revised labeling and to further studies on the safety of stimulants.

The AAP also advises that appropriate and consistent labeling about potential psychiatric side effects be developed and adopted by all manufacturers of stimulants.

Clinicians and their patients must weigh the potential risks and the potential benefits of treatment with stimulants, of other available treatments, and of non-treatment.

On behalf of the American Academy of Pediatrics, I thank you for your attention.