From the Doctor's Office

The FDA Advisory Committee's Recent Decision: An Interview with Pediatrician Andrew Adesman

by Bryan Goodman, M.A.

In February an advisory committee of the U.S. Food and Drug Administration (FDA) voted (8-7-1) to recommend adding "black box" warnings to stimulant medications used to treat attention-deficit/hyper-activity disorder (AD/HD). *Attention!*® interviewed Andrew Adesman, M.D., on the committee's decision.

Q: The advisory committee was asked to consider ways to research the safety of these medications in light of spontaneous reports of death and cardiovascular problems in children and adults taking stimulants. Has a connection been established between the two?

A: No. At this time, there is no clear evidence that treatment with stimulant medication has resulted in these extremely rare instances of sudden death in otherwise healthy children and adolescents. The FDA, while committed to further study, acknowledged that no evidence of a direct causal relationship exists.

Q: Are you, as a pediatrician, alarmed by the advisory committee's recommendation?

A: Not alarmed—concerned. Like all physicians, I am concerned by the reports of a few rare cases of sudden death in youth treated with stimulants, and I think it is important that this issue be systematically studied. At the same time, I am reassured by the FDA analysis that suggests that there were less than two cases of sudden death per million youth treated each year with stimulant medications. This is an extremely low fatality rate—and is, in fact, perhaps even lower than the sudden death rate in youth *not* treated with stimulant medication.

Q: How should parents of children on a stimulant medication respond?

A: Parents of children or teens with AD/HD who are being treated with a stimulant medication must educate themselves about this issue and speak with their health care provider if they have any concerns. If a child has no known structural heart disease, unexplained loss of consciousness or immediate family members with a history of fainting or unexplained sudden death at a young age, then there is little, if any, reason for concern. The American Academy of Pediatrics (AAP) advises pediatricians that they should not change their approach to medical treatment of children with AD/HD. I agree with this recommendation. Stimulant medication can still be a part of the initial treatment plan for school-age children with AD/HD. Similarly, children and adolescents with the disorder who are already responding well to stimulant medication can remain on their medication.

Q: Although the focus has been on potential risk associated with medication, aren't there also risks associated with *not* medicating this disorder?

A: Recent research has shown that stimulant medication can be essential. For example, treatment with stimulant medication substantially reduces the risk that a teen or young adult will later smoke cigarettes, abuse alcohol or use illicit drugs. Other studies have shown that stimulant medications can have a profound, positive influence on the driving performance of teens and young adults with AD/HD—people who, as a group, are at markedly increased risk for moving violations and motor vehicle accidents. Effective treatment with stimulant medication likely saves hundreds, if not thousands of lives each year through improved driving performance. These broader benefits cannot be ignored. It would seem, in general, the risks associated with *not* taking medication are far greater than the risks that have been questionably linked to treatment with stimulant medication. ■

Andrew Adesman, M.D., is a pediatrician practicing in New York City. He is a former CHADD board member.

Bryan Goodman, M.A., is CHADD's deputy director of communications and media relations.