

FDA Hearing on Stimulants – March 22, 2006

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Stimulants Damage the Heart

In 1977, Drs. Vernon Fischer and Hendrick Barner wrote a Letter to the Editor at *JAMA*, in which they described the cellular changes associated with cardiomyopathy (enlarged heart) in a patient who had taken Ritalin for 4 ½ years. A tissue sample was obtained from the patient during open heart surgery. That biopsy demonstrated abnormal membrane accumulations in the left ventricle.

Curious to know if the Ritalin had played any role in these changes, Fischer later teamed with Theodore Henderson to conduct animal studies. A causal effect was confirmed. Ritalin in mice and rats produced the same kinds of membrane proliferation in the heart cells seen previously. These changes were consistent with the cardiomyopathy observed earlier in the human subject.

Strattera – America’s Most Famous “Non-Stimulant”

Strattera is classified as a *psychostimulant* by the World Health Organization. Because of its *stimulant* effects, Strattera has been adopted by neurologists as a treatment for narcolepsy. Because of its *stimulant* effects, Strattera has been investigated by clinical trialists as a potential treatment for obesity.

In January 2006, the Office of the Chief Medical Examiner in North Carolina reported the discovery of ventricular abnormalities in the hearts of two young people who died while taking therapeutic doses of Strattera. It is important for the FDA to appropriately characterize Strattera as a stimulant, and to issue warnings about its potential cardiovascular risks.

Stimulants Reduce Cortical Blood Flow

In 1984, researchers discovered that Ritalin reduced cortical blood flow in children with ADD. In 1994, a team at Brookhaven Laboratory in Long Island replicated this finding, when they administered Ritalin intravenously to a group of healthy volunteers. The participants experienced a 20-30% **global** reduction in cerebral blood flow. The investigators concluded that these changes were most likely due to direct, vasoactive properties of Ritalin. They warned that oral doses of the same drug might produce similar, but even longer lasting, decrements.

Although the neurovascular effects of Ritalin are seldom considered by physicians or the FDA, the neuroscientific evidence has been undeniably clear. Numerous studies have confirmed that Ritalin, like cocaine and other street drugs, impedes neurodevelopment and shrinks the brain. The drug-induced impairment of blood flow is a likely causal mechanism about which medical professionals and consumers must be warned.

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