FEDS RECOMMEND WARNINGS ON ADHD DRUGS

Friday, February 10, 2006
Associated Press

Note from Pastor Kevin Lea: For several years we have been putting out warnings to parents about Ritalin and other drugs which manipulate child behavior. These warnings have included the fact that Ritalin is a form of Methamphetamine, and is highly addictive.

We also warned (years ago) that there was evidence these drugs were damaging children's hearts and bodies. I only needed to do a simple google.com check to find volumes of information. So why has it taken so long for the Feds to come clean? The answer seems obvious. There are billions of dollars involved in this legalized drug trade and the dangers have been swept under the rug while children's bodies are becoming addicted to an otherwise illegal drug, and their hearts and lives are being destroyed.

It is my prayer that this "official" news will help God's people to be set free from the mental disorder tags being foistered upon them by the drug dealers of this psycho-babble society we live in.

WASHINGTON — Concerned about the risk of sudden death or serious injury associated with Ritalin and other stimulants used to treat attention deficit hyperactivity disorder, a federal advisory panel says the drugs should carry the most serious type of warning label.

The proposed "black box" warning would inform doctors, patients and parents of the uncertainty regarding the risk the drugs may pose to the cardiovascular system. The warnings could be rescinded if future studies fail to definitely establish any risk, officials said.

The surprise recommendation has caught the **Food and Drug Administration** off guard. The regulatory agency isn't obliged to follow the advice of its outside panels of experts but it generally does.

Its first move probably will be to ask another of its advisory committees to

study the issue further in March.

The FDA also may undertake short-term studies into the effect of the drugs on blood pressure, heart rate and the heart muscle itself, said Dr. Peter Gross, chairman of the FDA's Drug Safety and Risk Management advisory committee, which eventually did outline its thoughts on how to study the drugs.

First, however, the committee voted 8-7 to recommend requiring black box warnings on methylphenidates, which are sold as Ritalin, **Concerta**, **Methylin** and **Metadate**.

Ritalin is made by Novartis Pharmaceuticals Corp.; Concerta by Johnson & Johnson; Methylin by Mallinckrodt Pharmaceuticals; and Metadate by UCB.

The labels for the stimulants Adderall and Adderall XR, both amphetamines made by Shire Pharmaceuticals, have included the warnings since 2004.

An earlier 15-0 vote was to recommend the drugs include a medication guide for patients and parents. There was one abstention on each of the late Thursday votes.

"The committee plainly wanted to tell us certain things ought to be in labeling in a more forceful way," Dr. Robert Temple, director of the FDA's Office of Medical Policy, told reporters after the votes.

Gross said most of his colleagues on the panel believe their role is to protect the public.

When asked why he and his fellow advisers approved, albeit narrowly, a recommendation they hadn't been asked to consider, Gross said: "No. 1, because of the seriousness of the side effects — the sudden deaths. No. 2, there is a sense maybe the diagnosis of ADHD is being applied where it shouldn't be applied."

An FDA review of its own databases found reports of 25 deaths in children and adults treated with the increasingly popular medicines. The deaths occurred between 1999 and 2003. The review also detailed 54 cases of serious cardiovascular problems, including heart attack, stroke, hypertension, palpitations and arrhythmia.

The FDA said the few studies that have looked at longer-term use of ADHD drugs provide little information on those types of risks.

And the FDA's own analysis of the reports of death and injury only suggested a possible link between the drugs and cardiovascular problems,

said Dr. Kate Gelperin, a medical officer in the agency's Office of Drug Safety.

While the FDA sought recommendations on further studies, the panel urged action.

One committee member, Dr. Curt Furberg, a professor of public health sciences at the Wake Forest University Baptist Medical Center, said it would be "inappropriate, unethical behavior" not to disclose that there was uncertainty about the safety of the drugs.

Dr. Gerald Dal Pan, a division director in the FDA's Center for Drug Evaluation and Research, said current warnings are appropriate given the agency's current knowledge of the drugs.

Ritalin, approved by the FDA in 1955, is both safe and effective, Novartis said.

Doctors prescribe the drugs to about 2 million children and 1 million adults a month. Among 12-year-old boys, 9.3 percent take ADHD drugs, according to a federal survey.

The black box warning would not apply to Strattera, manufactured by Eli Lilly and Co. That drug is not a stimulant.